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**TRIPS and the Pharmaceutical Industry in Bangladesh:  
Towards a National Strategy**

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The present paper, **TRIPS and Pharmaceutical Industry in Bangladesh: Towards a National Strategy**, has been prepared under the CPD programme on **Trade Policy Analysis and Multilateral Trading System**. This programme aims at strengthening institutional capacity in Bangladesh in the area of trade policy analysis, negotiations and implementation. The programme, inter alia, seeks to project the civil society's perspectives on the emerging issues emanating from the process of globalisation and liberalisation. The outputs of the programme will be available to all stakeholder groups including the government and policymakers, entrepreneurs and business leaders, and trade and development partners.

The programme has received support from the **Canadian International Development Agency (CIDA)** and is being implemented in collaboration with the **Centre for Trade Policy and Law (CTPL)**, Ottawa, Canada.

The present paper titled *TRIPS and the Pharmaceutical Industry in Bangladesh: Towards a National Strategy* has been prepared by *Professor Tony VanDuzer, Department of Law, Ottawa University, Canada*. The paper was presented at a dialogue on the theme of *Doha Declaration on WTO-TRIPS and Public Health: What is in it for Bangladesh?* organised by the Centre for Policy Dialogue (CPD) held at BRAC centre INN Conference Room, Dhaka on December 15, 2002.

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## **TRIPS and the Pharmaceutical Industry in Bangladesh: Towards a National Strategy**

### **INTRODUCTION**

When the Agreement on Trade-Related Aspects of Intellectual Property (the *TRIPS Agreement*)<sup>1</sup> was concluded at the close of the Uruguay Round of multilateral trade negotiations in 1993, it represented a remarkable expansion of the international framework for intellectual property rights. It imposed enhanced standards for what Member states had to protect, including a requirement to protect pharmaceuticals by patents. It also established, for the first time, minimum standards for the enforcement of substantive intellectual property rights and subjected all of these obligations to binding dispute settlement.

In the negotiations on the agenda for the Uruguay Round, developing countries had resisted the inclusion of intellectual property.<sup>2</sup> Traditionally, developing countries have not defined their interests as being served by high levels of protection for intellectual property rights. To some extent, this was based on the view that intellectual property was more properly understood as the common heritage of human kind. As well, developing country reluctance was motivated by pragmatic concerns that higher levels of intellectual property protection would involve a substantial commitment of scarce government resources to the administration and enforcement of intellectual property rights and would produce a significant net outflow of royalties to foreign rights holders and increased domestic prices. Nevertheless, for reasons largely unrelated to any interest they had in intellectual property rights, the developing countries consented to the TRIPS Agreement as part of the WTO package.<sup>3</sup>

In the years following the completion of the Uruguay Round, a consensus among developing countries has emerged that the patent rights for pharmaceutical products guaranteed by TRIPS are a substantial impediment to the adoption of policies necessary to ensure affordable access to medicines for their people. The monopoly of patent holders allows them to impose higher prices for essential drugs on developing

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<sup>1</sup> Annex 1C to the Marrakesh Agreement establishing the World Trade Organization, (1994) 33 I.L.M. 81 [*TRIPS Agreement*].

<sup>2</sup> See, for example, statements by delegate of India, Note by the Secretariat, Meeting of Negotiating Group of 12-14 July 1989, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights including Trade in Counterfeit Goods, MTN.GNG/NG11/14, 12 September 1989, at para. 79.1.

<sup>3</sup> There were two critical bases for developing country participation in the TRIPS Agreement. Addressing intellectual property in the context of the Uruguay Round of trade negotiations held out the prospect for trade offs with other areas. Developing countries with little interest in intellectual property could seek trade concessions in areas important to them such improved access for their textiles and agricultural products in return for accepting intellectual property commitments. Also, some developing countries, particularly the newly industrializing economies, had become interested in improving intellectual property protection, not just to create incentives for domestic investment in innovation but, more importantly, to attract foreign investment and technology transfer. As discussed below, developing countries have subsequently questioned the benefits of this bargain.

country consumers.<sup>4</sup> Concerns about this aspect of patent protection have become increasingly urgent in light of HIV/AIDs and other pandemics in developing countries.

Prior to 2001, the developed countries emphasized other impediments to affordable access to medicines insisting on the importance of protecting patents to provide incentives to produce new and better drugs. Led by the United States and the European Union, they took a consistently strong position on the necessity for WTO members to bring their regimes into conformity with TRIPS, and, indeed, to guarantee levels of patent protection exceeding those required under TRIPS.<sup>5</sup> By 2001, however, propelled by the unified voices of developing countries, both developed and developing country Members of the WTO had embarked on a process at the WTO to consider whether changes to TRIPS were necessary to address concerns regarding access to medicines.<sup>6</sup>

At the Doha Ministerial Meeting in November 2001, the concerns of developing countries were clearly and formally recognized in the Ministerial Declaration on the TRIPS Agreement and Public Health [*Doha Declaration on TRIPS and Public Health*].<sup>7</sup> The Members agreed that TRIPS can and should be interpreted in a manner supportive of Members' rights to protect public health and promote access to medicines for all. There is now widespread consensus on the need to ensure that TRIPS adequately addresses access to medicines. Subsequent discussions in Geneva have centred on how this may be done — a remarkable change in developed country attitudes.<sup>8</sup> There is not yet, however, a consensus on a solution.<sup>9</sup>

A key issue for Bangladesh in this context is to what extent existing as well as possible new TRIPS rules create an opportunity for the development of policies to

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<sup>4</sup> As discussed below, access to affordable medicines is, however, a complex, multi-dimensional problem. Obstacles to access include patents but are also related to financing, supply and distribution systems and pricing practices by multinational drug businesses.

<sup>5</sup> The United States initiated dispute settlement proceedings based on alleged failure to comply with TRIPS against India (*India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, Report of the Appellate Body, AB-1997-5 (WT/DS50/AB/R))[*India Patents*], Brazil (*Brazil-Measures Affecting Patent Protection*, Request for Establishment of a Panel by U.S., 2001 (WT/DS199/3)) and Argentina (*Argentina - Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*, Request for Consultations by the U.S., 1999 (WT/DS171/1)). Outside of WTO dispute settlement, the United States has put pressure on other developing countries, including Ghana, and South Africa to provide protection higher than required by TRIPS. See, F.M. Abbott, "The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO," (2002) 5 J. Int'l Econ. Law 469, at 471 & 475 and P. Champ and A. Attaran "Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the U.S. Brazil Patent Dispute" (2002), 27 Yale J. Int'l L. 365 [*Champ & Attaran*].

<sup>6</sup> Frederick Abbot identifies the decision of the TRIPS Council to hold a special session on access to medicines in June 2001 as the starting point of the process (*ibid.*, at 481).

<sup>7</sup> November 12, 2001 (WT/NIN(01)/DEC/2)[*Doha Declaration on TRIPS and Public Health*].

<sup>8</sup> Abbott, above note 5, and S. K. Sells, "Post-TRIPS Developments: The Tension Between Commercial and Social Agendas in the Context of Intellectual Property Rights," (2002) 14 Florida J. Int'l L. 193.

<sup>9</sup> Recently, this consensus was evident at a meeting of 25 trade ministers held in Sydney Australia in November 2002 where agreement was reached on key issues related to compulsory licensing (Virginia Marsh "Cheap drugs for the poor deal boosts trade talks" Financial Times, 17 November, 2002, at 2). As discussed below, the deadline for agreeing on specific action on this issue, 31 December 2002, passed without any resolution. See note 65 and accompanying text.

encourage the growth of its domestic pharmaceutical industry. To date, the international community has not delivered an organized and useful response to the health crisis in developing countries. It would be imprudent for Bangladesh to depend on such a response in the future to improve access to affordable medicines.<sup>10</sup> One aspect of providing secure continuing access to medicines in Bangladesh could be the development of a strong national pharmaceutical industry. At the same time, a strong national industry may provide many high paying jobs and generate substantial export earnings.

This paper, seeks to set out the constraints and opportunities that TRIPS patent rules represent for Bangladesh regarding the strategies it may adopt to further develop its national pharmaceutical industry. The pharmaceutical industry in Bangladesh is already the largest in the least-developed countries, but it does not have the research capacity to invent new pharmaceutical products, nor does it have the imitative capacity to reverse engineer patented drugs in order to develop competing generic products.<sup>11</sup> Instead, the principal activity of the domestic industry is the final production of generic products using imported generic active ingredients. These products are sold primarily to the domestic market. Under TRIPS rules, the supply of generic active ingredients may be cut off as a result of TRIPS requirement that the developing countries in which most of the generic producers reside grant full patent protection by 1 January 2005. Bangladesh does not currently permit the patenting of pharmaceutical products. Patents on drugs would essentially preclude the production of generic competing products in Bangladesh. Under the Doha Declaration on TRIPS and Public Health, Bangladesh, along with all other least-developed countries, is not required to grant such protection until 2016. Given this context, will generic producers in other countries that do not benefit from the extension invest in building productive capacity in Bangladesh, and assist the domestic industry to acquire the skills to develop new generic drugs? Does the extended deadline mean that the industry can not only continue its existing final production business but also expand export sales, especially in other least developed countries that also benefit from the extension?

Finding answers to these important questions requires a close examination of the complex provisions of the TRIPS Agreement and the likely impact of the implementation of its obligations not only in Bangladesh but also in other countries. In order to provide an appropriate context for this examination, I will first describe the rationale for patent protection of pharmaceuticals and its flaws in relation to developing and least-developed countries.

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<sup>10</sup> Abbott is also of this view, above note 5.

<sup>11</sup> Typically generic drugs are developed by someone who reverse engineers a patented drug invented by someone else to discover its chemical composition and then creates their own drug based on the same chemical composition. For the purposes of this paper a “generic product” or “generic drugs” means pharmaceutical product that has the same chemical composition as another pharmaceutical product or would otherwise infringe the patent rights of a person owning a valid patent on the second product. Where no valid patent exists in a national jurisdiction (whether because the national law of that jurisdiction does not recognize patents on pharmaceutical products, the person entitled has not applied for a patent, or the patent has expired) or a compulsory licence has been issued, “generic products” and “generic drugs” refer to pharmaceutical products that would infringe if a valid patent did exist and was enforceable against the producer of the generic product or drug or anyone else exploiting the product or drug in that national jurisdiction.

## **BACKGROUND: RATIONALE FOR PATENT PROTECTION OF PHARMACEUTICALS**

Protection of pharmaceuticals by patents under national laws is justified by developed countries as being necessary to encourage investment in research and development leading to the invention and commercialisation of new products.<sup>12</sup> Without the benefit of patent protection, anyone who is able to acquire knowledge regarding the composition of a pharmaceutical product developed by someone else through reverse engineering can develop a competing generic product based on the same composition. Those who do so have a competitive advantage over the innovator because they have not incurred the research and development costs associated with creating the original product. They may sell their competing generic products at a price lower than the price the innovator needs to charge for the original to cover the additional costs he or she has incurred. Sales of generic products by someone other than the innovator reduce the economic benefit of innovation to the innovator since they are sales the innovator might otherwise have made. The incentive for the innovator to invest in research and development leading to new pharmaceutical products will be reduced to the extent that the return on such an investment may be eroded by competition from generic products.

Patents permit the innovator to exclude others from exploiting the new pharmaceutical product for a period of time and, as a result, to recover the costs of research and development. In this way, patents encourage innovators to innovate. In an international context, patents encourage foreign direct investment for the purposes of innovation and the exploitation of patented technology in countries that protect patents. A further justification for patent protection is that disclosure of the patent is a condition of obtaining the statutory monopoly represented by the patent. Disclosure may be of assistance to subsequent innovators who will seek to improve on the original product.

The theoretical and empirical underpinnings of this classical rationale for patent protection of pharmaceuticals may be questioned. First, while the new and better products resulting from innovation are clearly a benefit to society, at some point investment in innovation will not be as socially valuable as other investments. In theory, at some level of patent protection, investment in innovation will become excessive and patent protection should be less than that level. Unfortunately it is difficult to know how much innovation is excessive. Second, even assuming one was able to know what the optimal amount of innovation activity is, setting the scope, duration and other characteristics of patent protection to ensure that the optimal

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<sup>12</sup> For a more fully elaborated analysis of this problem of market failure in the case of goods containing intellectual property see S. Besen and L.J. Raskind, "An Introduction to the Economics of Intellectual Property Protection," (1991) 5 J. of Econ. Perspectives at 5-6, M. Hart, "Getting Back To Basics: Reinventing Patent Law for Economic Efficiency," (1994) 8 Can. Intell. Prop. J. 217; K. Dam, "The Economic Underpinnings of Patent Law," (1994) 23 J. of Legal Studies 247 [*Dam*]. The pharmaceutical industry, above all others, depends on patent protection because it is relatively easy to reverse engineer a pharmaceutical product. See R.P. Merges and R.R. Nelson, "On the Complex Economics of Patent Scope," (1990) 90 Columbia L. Rev. 839 [*Merges & Nelson*] and Report of the Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (London, 2002)[*Barton Commission*] at 31.

amount takes place is problematic.<sup>13</sup> One of the reasons for this is that, while high levels of intellectual property protection may encourage innovation in the first instance, the protection granted an innovator will act as a barrier to those seeking to develop innovations which build on his or her innovation as well as encouraging wasteful investment in the development of substitute technologies by those seeking to compete with the innovator.<sup>14</sup> In order to facilitate a continuous process of innovation at optimal levels consideration must be given to the need for access to innovations for subsequent innovators to use the patented product to take the next innovative step.<sup>15</sup> While such use may always be allowed with the consent of the patent holder, the patent holder has an incentive to use the patent monopoly to refuse consent at any price since second stage innovators often will be competitors of the patent holder.<sup>16</sup>

Moreover, in addition to whatever benefits to creators and the public may result from pharmaceutical innovations stimulated by patents, there are also significant costs associated with granting patents. These are the costs associated with all monopolies: decreased production, higher prices, and more limited product differentiation.<sup>17</sup> In terms of prices, there is strong evidence that prices fall when drugs go off patent. The degree of price reduction depends on the number of generic competitors.<sup>18</sup> There is also the public cost of administering a patent system. A state must generate and continually update its laws dealing with intellectual property as well as providing the legal infrastructure for registering and enforcing patents.

In terms of setting national policy, the costs associated with patents and the benefits of patent protection are notoriously difficult to measure. Economists have had difficulty describing the precise ways in which the incentives created by patents operate.<sup>19</sup> There is no consensus on the magnitude of the effect of patents on research and development, much less on economic growth or social welfare. While, in theory, weak intellectual property protection reduces incentives to innovate, one cannot

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<sup>13</sup> D. McFetridge and M. Raffiquzzaman in "The Scope and Duration of the Patent Right and the Nature of Research Rivalry," (1986) 8 Res. L. & Econ. 91 address this issue.

<sup>14</sup> Merges & Nelson, above note 12; Economic Council of Canada, *Report on Intellectual and Industrial Property* (Ottawa: Information Canada, 1971) at 36.

<sup>15</sup> Merges and Nelson, *ibid.*, at 868-884. See also E. Kitch, "The Nature and Function of the Patent System," (1977) 20 J. L. & Econ. 265, for a differing view.

<sup>16</sup> An example of the conflict between those securing a patent right and subsequent innovation is the conflict between plant breeders and the research and agricultural sectors. Plant breeders favour broad patent protection for plant varieties while the research and agriculture communities fear that such high levels of protection would limit their access to new varieties (Science Council of Canada, *Innovation and Intellectual Property Rights in Canada* (Ottawa: Science Council of Canada, 1990), at 23-5).

<sup>17</sup> K. Maskus, "Economic Analysis of Intellectual Property Rights: Domestic and International Dimensions," in GLOBAL RIVALRY AND INTELLECTUAL PROPERTY: DEVELOPING CANADIAN STRATEGIES (Toronto: Institute for Research on Public Policy, 1990), at 121-122. Dam, above note 12, at 249-253.

<sup>18</sup> Barton Commission, above note 12, at 36. The absence of patent protection in India after 1970 stimulated the development of one of the world's strongest generic industries. See T. Ali, "Intellectual Property: Its Implications for Economic and Cultural Growth," presented to Centre for Policy Dialogue, *Dialogue on Doha Declaration on WTO-TRIPS and Public Health: What is in it for Bangladesh?* held in Dhaka, Bangladesh December 15, 2002 [Ali], at 5)

<sup>19</sup> Indeed some commentators have noted that economists have come to diametrically opposite conclusions on the manner in which intellectual property rights work (See J. Boyle, "A Politics of Intellectual Property" Working Paper, Legal Theory Workshop Series, University of Toronto, Faculty of Law, September 1996).

justify theoretically, empirically or in any other way the 20-year patent monopoly set out in TRIPS as optimal for global welfare.

In addition to these general problems with the rationale for patent protection, there are various concerns about patents specific to developing and least-developed countries. Patent rules will not benefit all countries in the same way that liberalizing rules for trade in goods and services will.<sup>20</sup> It is impossible to generalize regarding the impact of moving to stronger patent protection on economic growth in developed and developing countries or even amongst developing countries. There will be both costs and benefits, and they will vary from one country to the next. The “one size fits all” approach in the TRIPS Agreement fails to acknowledge this basic reality.

One key variable affecting the benefits of patent protection in a particular country will be to what extent patent protection will encourage domestic businesses to innovate. The economic benefits from patent led innovation will be small where local producers lack innovative capacity.<sup>21</sup> Another key factor affecting the impact of stronger patent rules will be the responsiveness of foreign investors. Strengthened patent protection can encourage the flow of technologies and products from developed to developing countries through licensing and foreign direct investment. Some recent evidence suggests that improved intellectual property rules did result in increased foreign direct investment in Chile and Malaysia. In most research to date, however, it has proven difficult to isolate effects related to intellectual property rights as distinct from other locational advantages for foreign investors.<sup>22</sup> Uncertainty regarding the benefits of intellectual property protection reduces developing country interest in spending scarce state resources on the recognition and enforcement of intellectual property rights.

Finally, market-based incentives like patents are likely to be inadequate to stimulate optimal levels of innovation by foreign or domestic firms to meet the needs of poor countries. Patent rights will encourage investment in developing new and better pharmaceutical products for which there is sufficient commercial demand. Patent rights will not stimulate investment in improvements to medicines to treat diseases suffered primarily by resource poor consumers in developing countries. Other policies integrated into a broad based program promoting public and private investment in technology and human resources through education and skills development, as well as publicly funded research will be needed to support development of such products.<sup>23</sup>

As discussed in more detail in the remainder of this paper, the inherent weaknesses of the classical rationale for patent protection of pharmaceuticals, and its particular inapplicability to a least-developed country like Bangladesh, means that developing national strategies to benefit from the patent obligations in TRIPS is a complex and daunting challenge.

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<sup>20</sup> M. Trebilcock and R. Howse, *THE REGULATION OF INTERNATIONAL TRADE*, 2d ed. (London: Routledge, 1999), at 310-312.

<sup>21</sup> As discussed below, this is the case currently in Bangladesh. *See* below note 81 and accompanying text.

<sup>22</sup> Indeed one study suggests that weak intellectual property protection encourages foreign direct investment since foreign intellectual property rights holders will choose this form of market entry over licensing because it gives them greater control over the exploitation of their intellectual property (*Intellectual Property and Foreign Direct Investment* (Geneva: UNCTAD, 1973).

<sup>23</sup> Barton Commission, above note 12, at 31-2.

## FROM TRIPS TO DOHA AND BEYOND: THE INTERNATIONAL REGIME FOR PATENT PROTECTION OF PHARMACEUTICALS

The following paragraphs describe each of the basic TRIPS obligations relating to the patent protection of pharmaceuticals as well as the Doha Declaration on TRIPS and Public Health which addressed some aspects of how those TRIPS provisions are to operate. As well, the possible future evolution of the TRIPS rules is discussed. The purpose of this section is to sketch the framework of international rules which define both the context within which the pharmaceutical industry in Bangladesh must operate, and the scope for Bangladesh to establish policies to promote the development of the domestic industry.

### 1. The Obligation to Provide Patent Protection

The TRIPS Agreement requires that WTO Members make patent protection available to products and processes in all fields of technology, including pharmaceutical products, wherever invented for 20 years from the date the application for patent protection is filed. Patents for processes must extend to products directly obtained from the process.<sup>24</sup> Patent protection for a product must give the owner the exclusive right to prevent third parties from “making, using, offering for sale, selling, or importing for these purposes” the product without the owner’s consent.<sup>25</sup> Members must require that an applicant for a patent disclose the invention in a manner sufficiently clear and complete to permit the invention to be carried out by a person skilled in the art. Members may require an applicant to provide information concerning the applicant’s corresponding foreign applications and grants.<sup>26</sup>

Members can refuse to grant patents for inventions if their commercial exploitation would endanger *ordre public* or morality, including human, animal or plant life or health or the environment. Members can also exclude from patentability diagnostic, therapeutic and surgical methods, plants and animals (other than micro-organisms) and biological process for the production of plants or animals (other than micro-biological processes).<sup>27</sup>

For developed countries, such as Canada, these obligations became binding on January 1, 1996.<sup>28</sup> Developing countries, such as India, were given until 2000 to bring their national regimes into compliance with TRIPS. Developing country Members, like India, that did not make available patent protection for pharmaceutical products benefited from a special transition period extending the deadline for the granting of patent protection for pharmaceutical products to 2005.<sup>29</sup> In the case of least-developed countries, like Bangladesh, TRIPS provides that they are not obliged

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<sup>24</sup> TRIPS Art. 27.

<sup>25</sup> TRIPS Art. 28.1. As discussed below, the importation right is subject to Art. 6 which, in effect, provides that each country is free to establish national rules regarding when a product sold or otherwise disposed of in one jurisdiction may thereafter be imported into another. See “Exhaustion and Parallel Importing” below notes 66 & 67 and accompanying text.

<sup>26</sup> Disclosure is required under TRIPS Art. 29. For the most part, TRIPS does not address the administration of national patent regimes.

<sup>27</sup> TRIPS Art. 27.2 and 27.3.

<sup>28</sup> TRIPS Art. 65.1.

<sup>29</sup> TRIPS Art. 65.4.

to grant patent protection or comply with most other obligations until 2006.<sup>30</sup> In the Doha Declaration on TRIPS and Public Health issued by the Ministerial Conference Meeting at Doha, Qatar in November 2001, the Members of the WTO agreed that least-developed country Members will not be obliged to implement TRIPS obligations regarding patents on pharmaceutical products or their enforcement until 1 January 2016. The right of least-developed countries to seek further extensions under Article 66.1 of the TRIPS Agreement was also affirmed.<sup>31</sup>

## 2. Articles 7 and 8 – TRIPS Interpretive Rules

The TRIPS Agreement sets out several general principles to guide the interpretation and enforcement of TRIPS rules, including the rules regarding patent protection for pharmaceuticals. Article 7 establishes that the protection and enforcement of intellectual property rights should operate not just for the benefit of some developed nations who are net exporters of goods and services to which intellectual property rights attach but rather “to the mutual advantage of producers and users of technology in a manner conducive to social and economic welfare, and a balance of rights and obligations.” As well, intellectual property rights protection should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. Article 1 provides that in pursuit of these objectives Members are free to determine the appropriate method of implementing TRIPS provisions within their own legal system and practice.

Article 8 specifically contemplates that Members may adopt measures to promote the public interest in sectors of vital importance to their socio-economic and technological development. Article 8 is subject to an important proviso, however. Such measures must be consistent with the provisions of the TRIPS Agreement. Thus Article 8 is merely an interpretive guide, not an exception to rights otherwise guaranteed in the agreement.

In the small number of WTO dispute settlement cases to date, these provisions have been referred to as informing the interpretation of TRIPS.<sup>32</sup> The necessity of interpreting TRIPS in light of its objectives and purpose as expressed in Articles 7 and 8 was confirmed in the Doha Declaration on TRIPS and Public Health.<sup>33</sup>

## 3. WTO Members’ Ability to Impose Reasonable Limits on Patent Rights

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<sup>30</sup> TRIPS Art. 66.1

<sup>31</sup> Doha Declaration on TRIPS and Public Health, above note 7, para. 7. The extension also applies to obligations with respect to the protection of undisclosed information under TRIPS Art. 39. TRIPS Art. 66.1 gives the TRIPS Council authority to grant such extensions. The TRIPS Council confirmed the grant of the extension for all least-developed country Members on 27 June 2002. See below note 69 and accompanying text. At the same meeting, the TRIPS Council approved a waiver of the exclusive marketing rights under Art. 70.9, discussed below. The waiver was submitted to the General Council for approval on 8 July 2002. For some reason, exclusive marketing rights were not addressed in the Doha Declaration on TRIPS and Public Health.

<sup>32</sup> E.g., *Canada-Patent Protection of Pharmaceutical Products*, Complaint by the European Communities and their Member States, Report of the Panel, 2000 (WT/DS114/R)[*Canada-EU Patents*] at 153.

<sup>33</sup> DOHA Declaration on TRIPS and Public Health, above note 7, at para. 5(a). Such an approach is only declaratory of what customary international law would require in any case. See Abbott, above note 5.

TRIPS permits Members to create “limited exceptions” to the exclusive rights conferred by a patent. This provision recognizes that patent rights cannot be absolute. Some exceptions are necessary, such as an exception to permit the use of a patented invention for scientific experimentation, a common feature of national patent laws. This grant of flexibility is constrained, however, by two further requirements. Such exceptions cannot

- unreasonably conflict with the normal exploitation of the patent or
- unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.<sup>34</sup>

The scope of this provision was considered by a WTO dispute settlement panel in a challenge by the European Union to two provisions of Canada’s patent law.<sup>35</sup> In the interests of permitting producers of generic drugs to enter the market as soon as possible following the expiration of a patent, Canadian law provided two exceptions to the exclusive rights of the patent holder:

- any person can make or use a patented invention solely for uses reasonably related to the development and submission of information under Canadian law regulating a product (the “Regulatory Review Exception”), and
- any person can make or use a patented invention for six months prior to the expiration of the patent to manufacture and store articles intended for sale after the expiry of the patent (the “Stockpiling Exception”).<sup>36</sup>

The Regulatory Review Exception is intended to allow producers of generic drugs to obtain marketing approval for products based on a patented formulation prior to the expiration of the patent with a view to competing with the patented drug as soon as the patent expires. In the absence of this exception, a generic drug producer could only apply for marketing approval after the expiry of the patent. Evidence led in the case established that the time needed to obtain marketing approval for generic drugs in Canada was usually between three and six and one half years.<sup>37</sup> Generic drug producers who rely on this exception and obtain marketing approval can begin to sell their products as soon as the patent expires rather than having to wait out the additional period needed for marketing approval. The Stockpiling Exception is similarly designed to facilitate immediate participation in the market by producers of generic drugs upon the expiry of the patent by allowing them to build up an inventory of their product in advance of the expiry of the patent.

The Panel found that Article 30 created three distinct tests. In order to be permitted under Article 30, an exception to the rights of a patent holder (i) must be “limited;” (ii) must not unreasonably conflict with the normal exploitation of the patent and (iii) must not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. Also, because Article 30 creates

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<sup>34</sup> TRIPS Art. 30. The complete text of TRIPS Art. 30 is set out in Annex 1.

<sup>35</sup> In *Canada-EU Patents*, above note 32, Canada gave evidence that while patent applications are usually filed as soon as an invention is created, the process of development and regulatory approval of a drug takes a further eight to 12 years (at 147).

<sup>36</sup> *Patent Act*, R.S.C. 1985, c. P-4, ss. 55.2(1) & (2).

<sup>37</sup> *Canada-EU Patents*, above note 32.

an exception to the rights otherwise guaranteed, Canada was found to have the burden of establishing that Article 30 permitted its legislation.

The Panel determined that “limited” should be narrowly interpreted and defined by reference to the legal nature of the constraint imposed on the patent owner’s right, not its economic impact. Since there was no limit on the quantity of drugs that could be stockpiled within the six-month period, the Panel held that the Stockpiling Exception was not limited within the meaning of Article 30 and so was inconsistent with Canada’s obligations in relation to patent protection. By contrast, the Panel found that the Regulatory Review Exception was limited because use of the patented invention was only for purposes of obtaining regulatory approval, and not for commercial exploitation.

In considering whether the Regulatory Review Exception conflicted with the patent owner’s “normal exploitation,” the Panel determined that the patent owner’s “normal exploitation of the patent” means its commercial exploitation. The Panel found that the Regulatory Review Exception did not interfere with the patent owner’s normal exploitation because it did not permit sales or other commercial exploitation of the patent during its term. The Panel acknowledged that, in the absence of the Regulatory Review Exception, the period of exclusivity conferred by the patent would be extended in practice by the length of time required to obtain marketing approval for a generic competitor. In the Panel’s view, this was not an inherent characteristic of the patent but rather the “unintended consequence of the intersection of patent and product laws.”<sup>38</sup> Because it did not find that the Regulatory Review Exception was in conflict with the rights of patent owners at all, the Panel did not have to consider whether the Regulatory Review Exception was reasonable.

With respect to the third criterion, the Panel found that the legitimate interests of the patent owner are narrower than the full protection of all its legal rights to exclusivity. The Panel acknowledged that the effective term of a pharmaceutical patent was cut short by the amount of time that was required to obtain marketing approval for the patented product after filing the patent. The evidence before the Panel showed that this loss was between eight and 12 years. Nevertheless, the conflicting national practices with respect to whether this effective patent term reduction was required to be compensated in some way meant that avoiding this reduction was not a legitimate interest that the Panel was required to take into account.<sup>39</sup> Consequently, the Panel determined that the Regulatory Review Exception was permitted under Article 30.

The *Canada-EU Patents* case suggests that in any future dispute settlement proceeding challenging an exception to the exclusive rights of patent owners provided for in a national law, the protection for such an exception provided by Article 30 will be interpreted narrowly. At the same time, the case provides some useful guidance regarding what will be found to be acceptable. One of the criteria would appear to be to what extent an exception is found in the national patent laws of most WTO Members.

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<sup>38</sup> *Ibid.*, at 161.

<sup>39</sup> The Panel noted that the laws of the EU, US and Switzerland provide for restoration of patent terms to compensate for time lost due to the requirement for regulatory approval, while the laws of other countries, including Poland and Thailand, as well as Canada, do not (*ibid.*, at 169).

#### 4. WTO Members' Ability to Grant Compulsory Licenses

The ability of a state to grant compulsory licences has been one of the key issues in the debate about how patent rules may be designed so as not to impede access to medicines. Under a compulsory licensing regime, the state can require a patent holder to grant a licence to some third party or to the state itself on specified terms.<sup>40</sup> In the negotiations resulting in the TRIPS Agreement, the U.S. sought to eliminate Members' ability to grant compulsory licenses altogether. While TRIPS allows compulsory licensing, it imposes significant restrictions on the circumstances in which compulsory licenses may be granted designed to reduce the degree of interference with the patent holder's rights as much as possible. These restrictions include the following.<sup>41</sup>

- The prospective licensee must have attempted to obtain a licence from the patent holder on reasonable commercial terms and conditions and, after a reasonable time, not been successful in doing so. This requirement may be waived by a Member in the case of "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use." Even in these situations, however, the patent holder must be notified as soon as possible of the licence.
- The use authorized in the licence shall be "predominantly for the supply of the domestic market of the Member authorizing its use."

Members are not obliged to apply these first two conditions where the use is authorized to remedy a practice determined to be anti-competitive after a judicial or administrative process.

- The scope and duration of the use authorized in the licence shall be limited to the purpose for which it was authorized. The license must be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent national authority shall have the authority to review the continued existence of these circumstances.
- The use must be non-exclusive.
- The patent holder must be paid adequate remuneration, taking into account the economic value of the rights licensed.
- The legal validity of any decision relating to the authorization of the licence shall be subject to judicial review or other independent review.

TRIPS does not specify the grounds upon which a compulsory licence may be granted. The Doha Declaration on TRIPS and Public Health confirms the unlimited flexibility of Members to determine when to issue a compulsory licence, subject to compliance with the above noted requirements.<sup>42</sup>

For some large developing countries with well-established and sophisticated pharmaceutical industries, like Brazil and India, compulsory licensing of local producers will be a viable strategy to obtain better access to medicines within the country. Where the patent holder is not willing to lower prices to an affordable level, a compulsory licence permitting a local firm to produce the patented drug may be

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<sup>40</sup> Compulsory licenses are granted under some national legal systems if, for example, a patent has not been worked in the country or to promote distribution and availability.

<sup>41</sup> The complete text of TRIPS Art. 31 is set out in Annex 1.

<sup>42</sup> Doha Declaration on TRIPS and Public Health, above note 7, para. 5(b).

granted.<sup>43</sup> For most developing countries, however, there simply are no local producers to licence. For compulsory licensing to be effective to introduce a more competitive market for drugs in these countries, licenses must include the right to import from foreign producers of generic drugs. There is a general consensus that Members may issue compulsory licences to import under Article 31.<sup>44</sup>

Frequently, however, granting a compulsory licence to import will not assist developing countries seeking to acquire medicines at low cost. The challenge for developing countries is to find a reasonably priced source of foreign supply. Where generic competition operates as a result of absence of patent protection in particular national markets, generic producers in these markets may be able to make drugs available to an importing country for lower prices. India, for example, does not currently grant patents on pharmaceutical products and India's producers are able to export to other markets where either product patents are not provided, such as in Bangladesh, or compulsory licenses for importing have been granted. After 2005, however, the ground rules for this trade change fundamentally. By this date, India must provide full product patent protection. Indian producers will not be able to continue to supply other countries with drugs protected by patents in India. India may grant compulsory licences for local production, but, in order to comply with TRIPS, any compulsory licence must be "predominantly for the supply of the domestic market." Thus, a compulsory licensee could only export the non-predominant portion of its production.<sup>45</sup> To permit countries in need of low cost medicines to acquire imports through compulsory licensing, it may be necessary for other countries with strong generic drug industries, like India, to be able to grant compulsory licenses allowing their producers to export a substantial proportion of their production. Currently, this would be contrary to TRIPS Article 31(f).<sup>46</sup>

At Doha, the concerns of developing countries regarding TRIPS compulsory licensing rules were addressed in the Doha Declaration on TRIPS and Public Health, though no amendments to the TRIPS Agreement were committed to. In the Doha Declaration on TRIPS and Public Health, the TRIPS Council, the WTO body responsible for the operation of TRIPS, was directed to find a solution by December 31, 2002 to the problem faced by developing countries with insufficient capacity for pharmaceutical manufacturing to make effective use of compulsory licensing.

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<sup>43</sup> There is ample evidence of the price reductions resulting from competition from generic drug producers. For example, prices for pharmaceuticals in countries in which patent protection is granted are up to 41 times higher than in India, where there is no patent protection currently. This evidence is summarized by K. Balasubramaniam in "Access to Medicines and Public Policy Safeguards under TRIPS" presented at the Centre for Policy Dialogue's Multi-Stakeholder Dialogue on Trade, Intellectual Property and Biological Resources in Asia (Dhaka, 19-20 April 2002)[Balasubramaniam].

<sup>44</sup> This right is even acknowledged by the U.S. See Second Communication from the United States, 25 June 2002 (IP/C/W/358)[*Second Communication from the US*]. As discussed below, the Bangladesh industry has limited capacity to develop and produce generic pharmaceuticals.

<sup>45</sup> There is no accepted interpretation of what "predominantly for the supply of the domestic market means." Abbott, above note 5, has suggested it could mean that at least half of production is for the domestic market, or only that production for the domestic market exceeds that for any single national export market (at 499).

<sup>46</sup> For Bangladesh, the extension of the deadline for granting patent protection for pharmaceutical products means that Article 31(f) imposes no limit on what Bangladesh may permit its producers to do until 2016. As discussed below, Bangladesh producers would be free to export, so long as the importing country is permitted to import either because patent protection does not exist or a compulsory licence has been issued there.

Subsequently, various proposals regarding how this might be done have been discussed in the TRIPS Council, including the following:

- Amending Article 31 to delete the requirement for compulsory licences to be predominantly for the supply of the domestic market;<sup>47</sup>
- Adopting an agreed interpretation that Article 30 permits Members to allow exports by persons, other than the patent owner, to countries in need, as a limited exception to the exclusive rights of the patent owner.<sup>48</sup>
- A waiver of the requirement under Article 31(f) that licences be predominantly for the supply of the domestic market.
- Agreeing to a moratorium on dispute settlement cases challenging compulsory licences to export in certain circumstances.<sup>49</sup>

The December 31, 2002 deadline passed without a consensus on how to resolve the problem.<sup>50</sup>

Each proposed solution would have advantages and disadvantages. An amendment to Article 31(f) of the TRIPS Agreement to permit the issuance of a compulsory licence for the export of pharmaceuticals to another member to address public health concerns in the other member would provide a durable solution based upon which governments could develop health care policy. As well, there is a clear process for amendment in the WTO Agreements.<sup>51</sup> On the other hand, it raises the prospect of the delicate balance represented by the TRIPS Agreement being disturbed and a broader discussion of amendments initiated.

Whether or not a broader discussion of TRIPS reform could be avoided, amending Article 31(f) has some practical drawbacks. Relying on compulsory licensing to provide affordable access to medicines would mean that a compulsory licence would have to be issued for each individual drug in both the exporting and importing country

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<sup>47</sup> E.g., Communication from the European Communities and their Member States, 20 June 2002 (IP/C/W/352).

<sup>48</sup> E.g., Communication from Brazil on behalf of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela, 21 June 2002 (IP/C/W/355)[*Communication from Brazil*].

<sup>49</sup> E.g., Second Communication from the United States, above note 44.

<sup>50</sup> Apparently, all countries but the U.S. agreed on a solution. The U.S. did not agree on the conditions, which would have to be satisfied for a country to be allowed to grant a compulsory licence to export. Subsequently the U.S. unilaterally announced that it would not initiate dispute settlement to enforce Art. 31(f) against any country issuing a compulsory licence to export in specified circumstances as discussed below note 64 and accompanying text (Communication from the United States: Moratorium to Address Needs of Developing and Least-Developed Members with No or Insufficient Manufacturing Capacities in the Pharmaceutical Sector, 10 February 2003 (IP/C/W/396/Corr.1) [*US Dispute Settlement Moratorium*]).

<sup>51</sup> Article X of the WTO Agreement sets out the process to be followed to amend the TRIPS Agreement. The details of this process are discussed in Note by the Secretariat: Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation, 23 July 2002 (IP/C/W363/Add.1)[*Secretariat Compilation*]. Essentially, the TRIPS Council or any Member may submit a proposed amendment to the Ministerial Conference or, between conferences, the General Council, which would then attempt to decide by consensus if the amendment should be submitted to Members. If consensus is not reached within 90 days (or any longer period agreed on), the amendment will be submitted to Members if doing so is approved by a 2/3 vote. Members may accept an amendment by depositing an instrument of acceptance the Director-General of the WTO within a period specified by the Ministerial Conference or General Council. The amendment comes into force when 2/3 of Members have accepted it for those members and on acceptance for the remaining Members.

to the extent that national patent protection for the drug existed.<sup>52</sup> Access to drugs would not be within the sole control of the importing country in need but would depend on the exercise of government discretion in another state to issue a licence to export. It would also involve a significant administrative burden, which would be onerous for the exporting and importing country alike. The problem of the payment of compensation to the patent holder in both jurisdictions has been raised as an additional concern.<sup>53</sup> Would the requirement to pay adequate remuneration based on the economic value of the licence mean that the licensee would have to charge prices similar to those charged by the patent owner in order to cover its costs? If so, compulsory licensing will not have much impact on access to medicine. In the absence of agreement on what economic value means in this context, the effect of this requirement is, at best, uncertain.

There are several related concerns, which may have to be addressed in any such amendment. Would there be a requirement that the right holder be notified and given an opportunity to negotiate to supply the market in the importing country member at a lower price? Such a requirement, which has been suggested by the European Union, would add to the administrative burden of compulsory licensing.

The most critical developed country concern is that low-priced pharmaceuticals imported into one country under an amended Article 31(f) will find their way into third country markets and compete with the products of the patent holder. Developed countries have suggested that requirements must be imposed on an importing country Member with respect to ensuring that re-export to other national markets is not permitted. These requirements could impose a substantial administrative burden on importing states.

Another issue is whether Members will be able to decide for themselves whether they are in a health care situation such that other Members are permitted to grant a compulsory licence to export to them or will they have to meet certain criteria? The following types of criteria have been discussed:

- limits on level of development of the importing country;
- limits on domestic capacity to produce pharmaceuticals in the importing country; and
- limits on products or diseases qualifying for compulsory licences to export.<sup>54</sup>

The value to importing country Members of allowing other Members to grant compulsory licences for the export of pharmaceuticals to them will depend on the conditions that are attached.<sup>55</sup>

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<sup>52</sup> This is a function of the requirement that compulsory licences must be granted on a case-by-case basis (Art. 31(a)). As discussed below, in some proportion of cases there will be no patent in either the exporting or importing country or both.

<sup>53</sup> Communication from Brazil, above note 48.

<sup>54</sup> It was reported that 25 Trade Ministers meeting in Sydney on November 17, 2002 agreed that each country should be able to define for itself whether they meet these criteria. This appeared to represent a significant change in the US position (Virginia Marsh “Cheap drugs for the poor deal boosts trade talks,” above note 9). As discussed below, ultimately, the U.S. did not agree that countries should have this right. See below note 65 and accompanying text.

<sup>55</sup> Communication from Brazil, above note 48, suggests that Art. 31(f) could simply be deleted. Some have questioned the significance of compulsory licensing as a policy measure. Amir Attaran notes that since TRIPS came into force, not one compulsory licence has been issued in the Southern hemisphere,

The alternative of adopting an interpretation of Article 30 which permits Members to allow producers to export drugs subject to patents for the purpose of addressing health crises in importing countries would avoid the administrative burden of issuing a compulsory licence in the exporting country. To the extent that it could be implemented through a ministerial decision, it would likely be more expeditious to adopt such an interpretation than obtaining an amendment.<sup>56</sup> Under such a solution, national patent laws could simply be amended one time to permit such exports.<sup>57</sup>

There are significant difficulties with this approach as well, however. First, it is not clear that such an “interpretation” is properly available given the clear language of Article 31(f). As well, the requirement in TRIPS Article 27.1 that patents be available without discrimination as to field of technology could be interpreted as prohibiting a national patent law provision that limited patent rights for pharmaceutical products.<sup>58</sup> Second, any interpretation would have to address the same sorts of concerns noted in the preceding discussion regarding the proposal to amend Article 31(f).<sup>59</sup>

The final mechanisms proposed are a moratorium on dispute settlement cases and a waiver of the obligation in Article 31(f). A waiver may be adopted by the Ministerial Conference or the General Council with respect to any obligation under the TRIPS Agreement “in exceptional circumstances” which must be identified in the waiver.<sup>60</sup> If the waiver is to extend for a period exceeding one year, it must be reviewed by the Ministerial Conference or the General Council not later than one year after it is granted and thereafter annually. The necessity of this annual review would seriously undermine the ability of Members to develop long-term health policy. Public and private investment decision-making would be frustrated by the risk that the waiver would not be renewed. The United States which supports the use of a waiver or moratorium has suggested that amendments and agreed interpretations are not as effective because how they apply to any particular case may only be known at the

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though the threat of compulsory licensing has been used successfully to negotiate price concessions from patent owners in some cases (A. Attaran, “The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals and Options under WTO Law,” (2002) 12 *Fordham Intellectual Prop., Media & Entertainment L. J.* 859 [Attaran]). See also *Human Development Report, 2001* (Geneva: United Nations, 2002)[*Human Development Report, 2001*].

<sup>56</sup> Article IX:2 of the WTO Agreement provides that the Ministerial Conference and, between conferences, the General Council (Art. IV.2) have exclusive authority to adopt interpretations of TRIPS. No interpretation can go so far as to amend provisions of TRIPS. No interpretation has ever been adopted. Decisions on interpretations are to be arrived at by consensus or, in default of consensus, by approval of ¾ of Members. See *Secretariat Compilation*, above note 51.

<sup>57</sup> There is some debate regarding whether a compulsory licence would still be required in the country of import. Some argue that a country may permit imports produced abroad under a compulsory licence under the doctrine of exhaustion discussed below. See note 66 and accompanying text.

<sup>58</sup> This position is taken by the United States in its Second Communication, above note 44. See similarly, Attaran, above note 55. Attaran also notes that an interpretation that allowed the manufacture and export of generic versions of patented pharmaceuticals to developing countries and not to developed countries could be inconsistent with the most-favoured nation obligation in TRIPS Art. 4. The one WTO case considering Art. 30 has said it should be interpreted narrowly (*Canada–EU Patents*, above note 32).

<sup>59</sup> An amendment to Article 30 addressing this specific point would be another way of resolving this problem, though there are no current advocates for this position.

<sup>60</sup> WTO Agreement, Art. IX.3 and IX.4. To date, there have been in excess of 140 waivers. See *Secretariat Compilation*, above note 51.

conclusion of a dispute settlement case.<sup>61</sup> It seems unlikely, however, that a waiver or moratorium would avoid this problem. Formulating the terms of the waiver or moratorium would require addressing the concerns noted in the preceding discussion of amending Article 31(f).<sup>62</sup>

A moratorium on dispute settlement is contemplated in various WTO Agreements in specific situations, but there is no express procedure, short of an amendment to the relevant agreement to impose a moratorium in relation to an existing provision of TRIPS or any other agreement. One commentator has suggested that a moratorium could be the subject of a Decision of the Ministerial Conference which may deal with all matters under any of the WTO Agreements.<sup>63</sup>

As noted, the Doha Declaration on TRIPS and Public Health directed the TRIPS Council to find a solution to the problem of how to ensure that the compulsory licensing rules in TRIPS allow developing countries without manufacturing capacity to obtain access to affordable medicines by the end of 2002.<sup>64</sup> Apparently, all countries but the U.S. agreed on a solution by the December 31, 2002 deadline. The U.S. could not agree on the conditions which would have to be satisfied for a country to be allowed to grant compulsory licences to export medicines. Subsequently, in February 2003, the U.S. unilaterally announced that it would not initiate dispute settlement to enforce Art. 31(f) against any country issuing a compulsory licence to export to a country so long as the importing country

- is not a “High Income Economy” as defined by the World Bank;
- is facing “a grave public health associated with HIV/AIDS, malaria, or tuberculosis or other infectious epidemic comparable scale and gravity”; and
- has no or insufficient production capacities in the pharmaceutical sector and has so notified the TRIPS Council.

All least-developed countries are deemed to meet the final criterion. All other countries will have to demonstrate that they meet it. The US Communication also specifies that all importing countries must issue a TRIPS compliant compulsory licence to import and, before doing so, must provide an opportunity for the patent holder to supply the needed products. Countries issuing compulsory licences to export must notify the TRIPS Council of each licence and make details of each licence publicly available. In order to prevent diversion, to qualify for the moratorium, all production under a compulsory licence which must be exported only to the intended country and the licensed manufacturers must provide the means by

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<sup>61</sup> Second Communication from the United States, above note 44.

<sup>62</sup> Indeed, the US Dispute Settlement Moratorium, above note 50, itself imposes a complex set of conditions which raise interpretive issues. See below note 64 and accompanying text

<sup>63</sup> Attaran, above note 55. He suggests that the moratorium could be implemented by Amending Appendix 2 to the Dispute Settlement Understanding which has been done on at least two previous occasions. This can be done by a decision of the WTO Ministerial Conference. Such decisions must be taken by consensus. The authority of the Ministerial Conference and the General Council to take decisions is set out in Art. IV:1 of the WTO Agreement. See *Secretariat Compilation*, above note 51. The moratorium on so-called “non-violation” complaints relating to TRIPS imposed by Art. 64.2 and discussed below was extended by a decision of the Ministerial Conference. See notes 73 & 74 and accompanying text.

<sup>64</sup> In its Second Communication, above note 44, the United States said that there appears to be an “emerging consensus on the key elements of a solution.” Recently, this consensus was evident at a meeting of 25 trade ministers held in Sydney Australia where agreement was reached on key issues related to compulsory licensing, as discussed below (Virginia Marsh “Cheap drugs for the poor deal boosts trade talks,” above note 9).

which the product can be identified, either by packaging, labeling or product characteristics, such as the shape or colour. Importing countries must take reasonable measures proportionate to their administrative capacities to ensure that medicines are not diverted into other markets.<sup>65</sup>

## **5. Exhaustion and Parallel Importing**

In the context of pharmaceuticals, parallel importing occurs where drugs that have been legitimately sold in one national market are imported by someone other than the patent holder into another national market in which they are protected by a national patent. Such parallel importing is permitted under the domestic laws of some countries. Under these laws, once drugs are sold legitimately in one country by the patent holder (or a licensee), the patent holder cannot thereafter assert patent rights in relation to those goods. The patent rights in the goods are considered exhausted when the goods are legitimately sold in the first national market and may be freely resold into a country permitting parallel importing. The justification for permitting parallel importing is that the patent owner has already been compensated on the first sale of the patented product and so should not be able to use the patent monopoly to block further sales.

Parallel importing has been touted as an important aspect of a regime designed to promote affordable access to medicines. Parallel imports compete with the patent holder's product. Where sales in a foreign market are at cheaper prices than those charged by the patent holder in the importing market, perhaps because the patent on the drugs has already expired in the foreign market, parallel imports can be cheaper than goods the patent owner is selling thus promoting more affordable access to medicines. At the same time, of course, parallel importing reduces the economic benefit of the patent to the rights holder.

TRIPS does not address when parallel importing should be permitted except in Article 6, which provides that for the purposes of dispute settlement, nothing in the agreement "shall be used to address the issue of exhaustion of intellectual property rights."<sup>66</sup> The Doha Declaration on TRIPS and Public Health affirmed that each Member has the right to establish its own rules regarding exhaustion of rights and parallel importing without challenge, subject to the MFN and national treatment obligations in TRIPS Articles 3 and 4.<sup>67</sup> One currently unresolved issue is whether this right means that Member's are free to permit the import of products sold in another country under a compulsory licence.

## **6. Transition Periods and Post-Box Rules**

As previously noted, developing countries benefit from certain transition periods in TRIPS.

- Developing countries and transition economies were given until 1 January 2000 to bring their legislation and practices into conformity with TRIPS.

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<sup>65</sup> US Dispute Settlement Moratorium, above note 50.

<sup>66</sup> The full text of Art. 6 is set out in Annex 1.

<sup>67</sup> Doha Declaration on TRIPS and Public Health, above note 7, para. 5(d).

- Developing countries which did not, at the close of the Uruguay round, provide product patent protection for pharmaceuticals or any other particular area of technology have until 1 January 2005 to introduce such protection.
- Least-developed countries have until 1 January 2006 to bring their legislation and practices into conformity with TRIPS and this deadline is extendible on request.<sup>68</sup>

With respect to patents for pharmaceutical products, in accordance with the Doha Declaration on TRIPS and Public Health, least-developed countries now have until 1 January 2016 to provide protection.<sup>69</sup>

There are certain special transitional rules that apply in the case of pharmaceutical and agricultural chemical products. Members that do not grant patents for such products relying on the transition periods described above must, nevertheless provide a means by which patent applications may be filed (called “mailbox applications”) from the beginning of the transition period. A Member is not obliged to consider granting a patent until the end of the transition period. When the transition period expires, each mailbox application is to be processed on the basis of its original filing date, applying the criteria for patentability as if those criteria were being applied on the filing date.<sup>70</sup>

This provision is designed to ensure that pharmaceuticals that could be patented if patent protection were available during the transition period do not cease to be patentable after the transition period has expired. In order to be patentable, a pharmaceutical must be “novel” at the time of the patent application, meaning that the product must not be part of the existing state of the art. A pharmaceutical being sold in a country during the transition period ceases to be novel and so, if not for the mailbox application system, would become ineligible for patent protection. By establishing a mechanism for filing applications during the transition period and then requiring that patent applications be assessed based on the application of the criteria for patentability at the date that the application is filed, the mailbox application system protects developers of pharmaceuticals from losing their right to patent their products during the transition period. The term of patent protection is calculated from the date the mailbox application is filed, even though protection only begins when the patent is granted.

Finally, if a mailbox application has been filed and authorization for marketing a pharmaceutical product is obtained in a Member during the transition period, the Member concerned must, subject to certain conditions, allow a patent owner to obtain an exclusive marketing right for the product for five years, or until a product patent is granted or refused, whichever is shorter.<sup>71</sup> The extension of the deadline for providing patent protection for pharmaceuticals for least-developed countries to 2016 decided on at Doha did not refer to their obligations to put in place a system of

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<sup>68</sup> TRIPS Art. 65. These extended transition periods do not apply to the basic national treatment and most favoured nation obligations in TRIPS Arts. 3 and 4.

<sup>69</sup> Doha Declaration on TRIPS and Public Health, above note 7, para. 7.

<sup>70</sup> TRIPS Art. 70.8. Where another priority date is available based on a convention, the criteria for patentability must be applied based on that priority date.

<sup>71</sup> TRIPS Art. 70.9. Also, in order to be able to obtain exclusive marketing rights, the applicant must have filed a patent application, been granted a patent and obtained marketing approval for the product in another WTO Member.

exclusive marketing rights. Subsequently, the TRIPS Council recommended to the General Council that a waiver be adopted regarding the exclusive marketing rights requirements.<sup>72</sup>

Finally, there is a transition period relating to WTO dispute settlement. The obligations of the TRIPS Agreement are subject to WTO dispute settlement procedures. TRIPS provided, however, that until January 1, 2000, only breaches of TRIPS could be the subject of dispute settlement procedures. A Member could not claim that a benefit accruing to it under TRIPS was being nullified or impaired by the measures of another Member where there was no conflict with a specific provision of TRIPS.<sup>73</sup> The WTO Ministerial Conference was empowered to decide, based on a recommendation of the TRIPS Council that this moratorium on such “non-violation” complaints should be extended. Prior to Doha, however, this matter was still under consideration in the TRIPS Council. At Doha, the Members directed the TRIPS Council to continue its examination of the appropriate “scope and modalities” for such complaints and make recommendations to the next Ministerial Conference in 2003. In the meantime, Members agreed not to initiate such complaints.<sup>74</sup>

## 7. Technical Assistance and Technology Transfer

In order to ensure that the least-developed countries receive benefits from TRIPS, Article 66.2 requires developed country Members to provide incentives to enterprises and institutions in their territories to promote and encourage technology transfer to least-developed country members. Many least-developed country Members have expressed their concern that developed country Members have not been fulfilling their obligations under this provision. The commitment of developed countries was affirmed in the Doha Declaration on TRIPS and Public Health.<sup>75</sup> In the Doha Decision on Implementation-Related Issues and Concerns, the Members affirmed the mandatory nature of these obligations and directed the TRIPS Council to put in place a mechanism to ensure monitoring and full implementation of the obligations. As well, all developed country Members were directed to submit detailed reports on the functioning in practice of the incentives they provide prior to the end of 2002. These reports are to be reviewed by the TRIPS Council and updated annually.<sup>76</sup>

## PATENT PROTECTION IN BANGLADESH

In Bangladesh, patents are protected under the *Patents and Designs Act, 1911*, as amended from time to time, and the *Patents and Designs Rules, 1933*.<sup>77</sup> Patent

<sup>72</sup> TRIPS Council Meeting, 27 June 2002 (IP/C/M36). The waiver was submitted to the WTO General Council on 8 July 2002.

<sup>73</sup> TRIPS Art. 64.2. These types of complaints are provided for under Art. XXIII.1(b) and (c) of the GATT 1994 Agreement.

<sup>74</sup> Decision of 14 November 2001: Implementation-Related Issues and Concerns (WT/MIN(01)/17)[*Doha Implementation Decision*], para. 11.1.

<sup>75</sup> Doha Declaration on TRIPS and Public Health, above note 7, para. 7.

<sup>76</sup> Doha Implementation Decision, above note 74, para. 11.2. The least-developed countries, including Bangladesh, submitted a communication to the TRIPS Council outlining the considerations which should be relevant to establishing a monitoring mechanism: Mechanism for Ensuring the Monitoring and Full Implementation of the Obligations under Article 66.2 of the TRIPS Agreement in Accordance with Paragraph 11.2 of the Doha Decision on Implementation-related Issues and Concerns, 25 June 2002 (IP/C/W/357).

<sup>77</sup> See generally, A.A. Khan, *THE LAW OF TRADE MARKS, COPYRIGHT, PATENTS AND DESIGNS* (Dhaka: New Warsi Book, 2002) for the text of the law and amendments.

protection can be obtained for the process of producing a pharmaceutical product but not for pharmaceutical products themselves.<sup>78</sup> A few patents for processes to produce pharmaceuticals have been issued. Product patents, however, are what multinational pharmaceutical businesses principally rely on in other jurisdictions. Compulsory licensing is permitted under the *Patents and Designs Act, 1911* where the demand for the patented product is not being met to an adequate extent and on reasonable terms in Bangladesh.<sup>79</sup> No compulsory licence has ever been issued.

As a least-developed country, Bangladesh has until 1 January 2016 to bring its patent regime into compliance with TRIPS by granting patent protection for pharmaceutical products. Bangladesh is obliged to have in place already a system to receive mailbox applications for pharmaceutical product patents. In all other areas of TRIPS, 1 January 2006 is the deadline for TRIPS compliance. Work is currently under way to make the necessary amendments to implement TRIPS' obligations.<sup>80</sup>

## THE PHARMACEUTICAL INDUSTRY IN BANGLADESH

The options that Bangladesh has under TRIPS depend, in part, on the nature and potential of the domestic pharmaceutical industry. Unfortunately, up to date information is not readily available on the current state of the pharmaceutical industry in Bangladesh. According to a study by the United Nations Industry Organization (UNIDO), Bangladesh's industry has the capacity to produce finished pharmaceutical products but lacks both the capacity to produce the key active or "therapeutic" ingredients for drugs and the innovative capabilities to reverse engineer drugs to develop generic competitors to patented products or to invent new drugs.<sup>81</sup> In this regard, UNIDO ranked Bangladesh at the same level as Brunei, Cambodia and Thailand but behind China, India and Indonesia. Some have suggested that the larger local firms may be able to develop their own generic drugs as soon as 2005.<sup>82</sup>

Generic versions of therapeutic ingredients are imported into Bangladesh usually from India and used to produce finished drug products.<sup>83</sup> For 1992, the latest year for which information was provided in the UNIDO study, the value of Bangladesh's output of drugs and medicines was US\$228 million representing an addition to value of US\$110 million.<sup>84</sup> For the year 2000, Bangladesh imported US\$84,000,000 worth of medicinal and pharmaceutical products and had negligible exports. Some recent

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<sup>78</sup> *Patent and Designs Act, 1911*, s. 3(e).

<sup>79</sup> *Patent and Designs Act, 1911*, s. 22.

<sup>80</sup> Trade Policy Review: Bangladesh – Secretariat Report 2000 (WT/TPR/S/68)[*Bangladesh TPR*].

<sup>81</sup> R. Ballance, J. Pogany, H. Forstner and E. Elgar, *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition and Policy* (UNIDO, 1992) cited in Note by the Secretariat: Available Information on Manufacturing Capacity for Medicines, 24 May 2002 (IP/C/W/345) [*Secretariat Note on Manufacturing Capacity*]. This view of the Bangladesh industry was confirmed in "Making Vital Medicines Available for Poor People: Bangladesh (London: Oxfam, 2000) [*Oxfam Report*], at 4.

<sup>82</sup> Statement by Samson Chowdhury, Chairman, Square Pharmaceuticals, at Centre for Policy Dialogue, "Dialogue on Doha Declaration on WTO-TRIPS and Public Health: What's in it for Bangladesh?" held in Dhaka, Bangladesh, December 15, 2002. Mr. Chowdhury suggested that physical resource constraints would likely make it impossible for local producers to engage in all stages of drug production. Basic ingredients would still have to be obtained abroad.

<sup>83</sup> Oxfam Report, above note 81, at 3, 4.

<sup>84</sup> This is the most recent information available from UNIDO according to the Secretariat Note on Manufacturing Capacity, above note 81.

statements by industry representatives suggest that exports will increase in the near future.<sup>85</sup>

To date, the absence of patent protection in Bangladesh and neighboring states, such as India, has done little to alleviate the desperate problem of access to medicines in Bangladesh. One constraint is limited public spending on health care. In 2000, per capita spending on health care was US\$70, compared to US\$3,724 in the United States. For most of the 1990's, public spending on health represented 1.6% of Gross Domestic Product.<sup>86</sup> Another constraint is the limited resources of the population. A high percentage of the population cannot afford drugs at any price.<sup>87</sup> Partly as a consequence of inadequate access to medicines, a recent Oxfam report described the health care system in Bangladesh as "failing."<sup>88</sup>

In this context, the local industry plays a critical role importing ingredients and doing the final production of pharmaceuticals which are then re-branded for sale in the Bangladesh market.<sup>89</sup> Foreign firms have not found it financially attractive to supply most segments of the Bangladesh market. A few foreign pharmaceutical companies are operating in the Bangladesh market selling a small number of higher priced products to wealthier consumers. Local firms, producing at lower cost, have been the principal suppliers of drugs to the Bangladesh health care system.<sup>90</sup>

In this situation, there are likely to be few benefits and significant costs to putting in place full patent protection for pharmaceutical products in advance of the 2016 deadline. The local industry would be precluded from importing generic drugs and ingredients for drugs, which are the subject of patents in Bangladesh. While, in principle, licensing agreements could be negotiated with proprietary drug manufacturers who own the patents to permit continued importation of ingredients and local production of finished products, inevitably, the cost to the industry and, ultimately, to Bangladeshi consumers would be high. Compulsory licensing would be subject to the strictures of TRIPS Article 31, including the payment of adequate compensation and severe limitations on the right to export. Also, at the moment, the local industry does not have the technical capacity to use a compulsory licence to produce a generic drug from scratch. Compulsory licences to import would be useful only if a cheap source of foreign supply can be found. As discussed below, implementation of TRIPS rules in other countries may make this difficult.

Any longer term benefits from patent protection associated with domestic and foreign investment in local production of pharmaceuticals, research and development, and technology transfer would seem speculative at best. Local innovation would be all but precluded by a lack of innovative capacity. Foreign investment by proprietary drug manufacturers may be attracted by low labour costs, but this advantage is

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<sup>85</sup> Statement by Samson Chowdhury, Chair, Square Pharmaceuticals, at Centre for Policy Dialogue "Dialogue on Doha Declaration on WTO-TRIPS and Public Health: What's in it for Bangladesh?" held in Dhaka, Bangladesh, December 15, 2002.

<sup>86</sup> Balasubramaniam, above note 43, at 7.

<sup>87</sup> While no reliable statistics were found, Oxfam cites one commentator as putting the percentage of the population unable to afford medicines at "at least 70%" (Oxfam, above note 81, at 4).

<sup>88</sup> Oxfam Report, *ibid.*, at 2.

<sup>89</sup> Many have cited the development of local industry in developing countries as an important aspect of providing access to medicines: *e.g.*, Oxfam Report, *ibid.*; Abbott, above note 5; Sells, above note 8.

<sup>90</sup> Oxfam Report, *ibid.*, at 7.

available in many places. Finally, the administrative costs of developing a system capable of handling a flood of patent applications from proprietary pharmaceutical manufacturers and granting compulsory licences to local firms would be significant. While, ultimately, these costs must be incurred, there is no apparent advantage to doing so voluntarily prior to 2016.

## **DEVELOPING A STRATEGY FRAMEWORK FOR BANGLADESH'S PHARMACEUTICAL INDUSTRY IN RESPONSE TO TRIPS**

If patent protection is not provided for pharmaceuticals in Bangladesh until 2016, what are the implications of the current TRIPS regime for the Bangladesh pharmaceutical industry and policies of the Bangladesh government to support it? Creating the conditions for the expansion of the local pharmaceutical industry in Bangladesh involves one set of considerations related to TRIPS for the period prior to 2016, and some additional considerations after that date.

### **1. Prior to 2016 – Exploiting TRIPS' transition periods**

#### ***Introduction***

Under the current regime and until 2016, Bangladesh is free to continue to permit the importation of pharmaceuticals, and the production and sale of pharmaceuticals in the domestic market whether or not they are patented elsewhere, so long as they are not patented in Bangladesh. As discussed above, only process patents may be issued under the current law and few such patents have been granted. This would seem to create a market opportunity for the further development of the local pharmaceutical industry as a producer of generic products during the transition period. Nevertheless there are a significant number of issues relating to the ability of the Bangladesh industry to take advantage of this apparent opportunity. The first major issue is how can Bangladesh ensure that its access to generic pharmaceutical ingredients is secure, especially given that the developing countries in which generic suppliers operate will be required to grant and enforce full product patent protection beginning in 2005, preventing the production of infringing generic products. The second issue is what will be the impact of TRIPS on the demand for generic Bangladesh products both in Bangladesh and in other countries. How these issues are resolved will have a significant impact on the ability of Bangladesh industry to exploit this apparent market opportunity and on the nature and effectiveness of Bangladesh government policies designed to facilitate the growth of the domestic industry. In the following section, a framework for analyzing these issues is developed and areas in which further research is required are identified.

#### ***Certainty of Supply of Basic Therapeutic Ingredients***

In its current state of development, Bangladesh's industry must import therapeutic ingredients, many of which are protected by patents in other countries. The principal suppliers of such ingredients are producers of cheaper generic products located in India and some other countries. By 2005, TRIPS requires India and other developing countries to provide full patent protection for pharmaceutical products and so firms from these countries will be unable to continue to supply these ingredients to the extent that they become subject to patents rights within the country. Only the patent

holder will be able to authorize production and export. Under the existing TRIPS regime, supplier countries may grant compulsory licences on patented pharmaceuticals to its domestic producers, but such licences must be predominantly for the supply of the domestic market. Consequently, even if compulsory licences were granted, the production available for export to Bangladesh would be limited.

As discussed above, by the end of 2002, the WTO was to have adopted some mechanism to permit Members to allow their producers more flexibility to supply the needs of other countries, such as Bangladesh, for purposes of safeguarding public health. While the deadline has passed, work continues to find a solution. The prospects for Bangladesh's industry to gain access to generic ingredients will depend on how this is done. The best outcome for Bangladesh would be one which imposed the fewest restrictions on the ability of Members, like India, to export to Bangladesh and provided the greatest certainty of supply to the existing industry. Certainty regarding the conditions for supply will be a key consideration for possible foreign and domestic investors alike.

Bangladesh would benefit from a regime in which India and other Members were able to amend their patent regimes once to permit generic producers to produce and export generic therapeutic ingredients to Bangladesh, without the requirement of granting a compulsory licence in each case. This could be based on an agreed understanding or amendment of Article 30. If countries put in place such amendments to their domestic law, there would be less risk that exports would be curtailed in the future through the actions of exporting states. Legislation is harder to change than a discretionary compulsory licence.

Currently, however, it seems more likely that some form of compulsory licensing will be required to permit exports to countries in need. The Bangladesh industry would have greater certainty that it would have access to a reliable supply of therapeutic ingredients if it had the right to decide for itself whether it was eligible to receive imports from countries granting compulsory licences to export under some modified TRIPS regime. It is clearly less desirable to have Bangladesh's eligibility for such exports depend on the satisfaction of some inevitably arbitrary objective criteria for public health needs and lack of local productive capacity, the application of which may be the subject of divergent views. Only if WTO rules permit Bangladesh to decide for itself whether it qualifies for exports under a modified regime permitting foreign compulsory licences to export can the Bangladesh government make credible commitments to investors that it will continue to be eligible.

At least in the short term, Bangladesh would also benefit if few restrictions were imposed to guard against re-export of the pharmaceuticals it imports. The administrative burden of putting place border measures to ensure that re-export was prevented could be very onerous.<sup>91</sup> If, however, drugs imported into Bangladesh find their way into third country markets and displace sales of patented drugs, the inevitable result would be enormous pressure on Bangladesh either to put in place effective protection or to cease importing altogether. Indeed, recent history suggests

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<sup>91</sup> Bangladesh's interests would also be served if there were no other administrative burdens associated with the decision that imports produced under a compulsory licence were required, such as requirements to notify the WTO as has been proposed by the United States (*Second Communication from the US*, above note 44).

that the US in particular but also the European Union and Japan will be aggressive in policing any new regime and likely to exert pressure on Members not to exploit fully any flexibility that does exist under the regime.<sup>92</sup>

There is some evidence to suggest that greater tolerance on the part of these countries has developed in the past few months regarding measures taken by developing countries related to public health.<sup>93</sup> The Doha Declaration on TRIPS and Public Health expressly affirms that Members have the right “to use, to the full, the provisions of the TRIPS Agreement” for purposes of protecting public health and promoting access to medicines. The precise legal status of the Declaration in this regard is not clear. While some consider that it may be simply a political statement,<sup>94</sup> others suggest that it is a binding decision of the Ministerial Conference.<sup>95</sup> At the very least, this aspect of the Declaration must be considered a supplementary means of interpreting the TRIPS Agreement.<sup>96</sup> Nevertheless, in practice, Bangladesh’s ability to receive exports will depend on whether it can credibly assure the other Members of the WTO that there will be no re-export.

Whatever solution is adopted to permit the export of pharmaceuticals without the patent owner’s consent, the ability of India’s producers and those in other countries with significant generic drug producing industries to supply Bangladesh will continue to depend on the autonomous policy choice of their governments. Bangladesh may be able to rely on the rational self-interest of India and others to permit exports so long as a profit can be made on such sales. The dependence of the supply of low priced generic drugs from India on Indian government policy with respect to compulsory licensing, however, will reduce incentives for investment in the Bangladesh industry. On its own, Bangladesh cannot ensure that adequate supplies are available.

Also, whether compulsory licenses to export will result in a cost effective source of supply will depend on the effect of the requirement for the generic producer to pay adequate remuneration to the patent owner. At some level, compulsory licence fees will increase the price of therapeutic ingredients to the point at which Bangladesh production becomes uneconomic. What fees will be charged will be a function of the requirements of TRIPS and decisions of government agencies in supplier states.

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<sup>92</sup> Abbott, above note 5; Sells, above note 8.

<sup>93</sup> The U.S., for example, in effect withdrew its WTO complaints against Brazil and Argentina regarding their patent laws (cited above note 3). President Bush has affirmed the policy of President Clinton adopted in 2000 that the US government would not put pressure on Sub-Saharan governments to change intellectual property policies that regulate HIV/AIDS pharmaceuticals. See Sells, above note 8, at 212-213. By contrast, in 1996 and 1997, it aggressively pursued its complaint about India’s failure to implement a mailbox system to a successful conclusion (*India Patents*, above note 5). US pressure on Ghana and Uganda is described in Oxfam Report, above note 81.

<sup>94</sup> S. Charnovitz, in “The Legal Status of the Doha Declarations,” (2002) 5 J. Int’l Econ. L. 207, suggests that this is one possible view of the Declaration but concludes that the status is ambiguous (at 211).

<sup>95</sup> Attaran, above note 55; Abbott, above note 5, at 491. The process for the adoption of authoritative interpretations of TRIPS is discussed above in note 56.

<sup>96</sup> C. Otero Garcia-Castrillon, suggests that the Declaration should be considered a supplementary means of interpretation under Art. 32 of the *Vienna Convention on the Law of Treaties* (U.N. Doc. A/CONF. 39/27 (1969)) in “An Approach to the WTO Ministerial Declaration on the TRIPS Agreement and Public Health,” (2002) 5 J. Int’l Econ. L. 212. It may also be considered a subsequent agreement between the parties which may be taken into account under Art. 31(3)(a) of the convention.

Until there is some consensus in the WTO about the circumstances in which Member countries can give permission to export to countries in need, like Bangladesh, it is impossible to assess concretely the magnitude of the impact of the imposition of patent protection in developing countries that are home to major producers of generic drugs. There is no doubt that supply will become less readily available and more expensive.

### ***Development of Capacity to Produce Therapeutic Ingredients***

In light of the uncertainty regarding the reliability of traditional sources of supply, Bangladesh could seek to develop its own capacity to produce therapeutic ingredients as an alternative to continued reliance on imported generic therapeutic ingredients. Such a strategy would provide local employment and technology transfer and, to the extent that production costs are lower in Bangladesh, could lead to reduced domestic prices. With the 2005 deadline looming for India and other countries, generic manufacturers in those countries may be encouraged to invest in production in Bangladesh, where they could continue to produce therapeutic ingredients and supply not only Bangladesh but also other countries in which protection is not yet granted. It is certainly possible, however, that governments in these countries would prefer to grant compulsory licences to export to these markets if this were permitted, rather than see the movement of productive capacity from India to Bangladesh. This suggests that, paradoxically, Bangladesh's domestic industry may be more attractive to foreign investors if TRIPS imposed tight restrictions on a Member's ability to grant compulsory licences to export.

To be successful, a strategy of developing domestic capacity to produce generic drugs would require both substantial technical assistance, as well as investment. Some have advocated that some assistance be channeled toward the development of local industry as an aspect of promoting affordable access to medicines.<sup>97</sup> To date, the development of local industries has not been the focus of international assistance efforts. International agencies like the WTO, the WIPO, and others have concentrated on helping countries conform their intellectual property rules to TRIPS while programs sponsored by other agencies, such as the current four-year World Bank program, have invested in needed improvements to health care infrastructure. For Bangladesh to be successful in enhancing the capacity of the domestic pharmaceutical industry to the point at which it could produce drugs without relying on imports of therapeutic ingredients, significant new programs would be required. Programs to enhance education and skills as well as public funding of research would all be needed. One possibility for facilitating the development of such programs would be to seek targeted assistance from developed country Members of the WTO in accordance with their obligations under TRIPS Article 66.2.

### ***Determinants of Demand for Bangladesh Products***

As noted, Indian and perhaps other foreign producers of generic drugs in developing countries be interested in investing in production in Bangladesh in anticipation of the 2005 deadline for putting place pharmaceutical product patent protection in those

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<sup>97</sup> Report of the Workshop on Differential Pricing and Financing of Essential Drugs, Hosbjor, Norway, 8-11 April 2001 [*Report of Hosbjor Workshop*].

countries and policies could be developed to encourage such investment. There are, however, a number of concerns tied to TRIPS which will affect the likely demand for the products produced by the domestic industry and which, as a result, will influence the attractiveness of investing in Bangladesh.

The prospects for the success of the domestic industry depend, not just on the domestic market of Bangladesh, but also on export sales. Currently, Bangladesh's exports are negligible. While there may be various explanations for this, it is likely that producers of generic pharmaceuticals in countries such as India and Brazil with very large and sophisticated industries supply most developing country export markets. After 2005, Indian firms and generic producers in most other WTO Member countries will be precluded from supplying pharmaceutical products subject to patents in the country of manufacture, strengthening the competitive position of existing producers of competing generic products in Bangladesh. These suddenly underserved markets in developing and least-developed markets represent export opportunities for Bangladesh producers and create an incentive for domestic and foreign investment in Bangladesh to develop productive capacity and to take advantage of these opportunities.

In principle, some other least-developed countries that do not provide patent protection could also seek to develop their national industries to the level at which they could produce products which would compete with products produced by Bangladesh in their own national markets, in Bangladesh and in third country markets. In practice, it is not clear that the development of the necessary productive capacity in any other least-developed country is contemplated or feasible. One of the advantages that Bangladesh has over most other least developed countries is a large size of its internal market. This makes it more attractive as a location for investment in developing productive capacity. As well, the existing industry is the largest among least-developed countries.<sup>98</sup>

TRIPS rules will, however, limit markets for Bangladesh exports. Bangladesh's producers cannot lawfully export generic products into national markets in which patent protection exists so long as Bangladesh production is not by or with the permission of the owners of patents on the products. Consequently export markets will be limited to those markets in which patent protection is not provided, because one of the following situations exists.

- A country is not a Member of the WTO and has not enacted patent protection for the pharmaceuticals.
- A country is a developing country or least-developed country Member of the WTO which has not yet enacted patent protection for pharmaceuticals in reliance on TRIPS transition periods.
- A country is a Member of the WTO, which provides patent protection to pharmaceuticals but has granted compulsory licences for the import of pharmaceuticals.

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<sup>98</sup> Statement by Samson Chowdhury, Chairman, Square Pharmaceuticals at Centre for Policy Dialogue, "Dialogue on Doha Declaration on WTO-TRIPS and Public Health: What's in it for Bangladesh?" held in Dhaka, Bangladesh on December 15, 2002.

- A country is a Member of the WTO and grants patent protection but the person who would be entitled to seek patent protection has not done so and no patent has been issued.<sup>99</sup>

As well, even after 2005, countries like India and Brazil may still be able to permit generic exports to some developing and least-developed countries depending on the mechanism that is ultimately put in place at the WTO to deal with permission to export without the consent of the patent holder. Consequently, prior to 2016, Bangladesh's export interests may be best served by tight restrictions on the circumstances in which such generic exports from Bangladesh's competitors would be permitted.

Assessing the viability of exporting pharmaceuticals from Bangladesh and the resulting impact on investment incentives would require an identification and assessment of the potential market of the countries in each category. Research to make such assessments will be necessary as a condition of developing a viable national strategy for promoting the domestic industry. As well, the prospects for existing generic producers to continue to serve those market under some new amendment or agreed interpretation of TRIPS would have to be factored in.

Perhaps the most fundamental concern regarding the viability of any strategy to grow the domestic pharmaceutical industry is the purchasing power of consumers in Bangladesh and in other developing country markets to purchase Bangladesh's drugs. There is significant evidence that most consumers in such markets cannot afford to pay even the costs of physical production by developing country producers.<sup>100</sup>

Increased public spending to acquire drugs for national distribution would help to ensure a market for Bangladesh produced pharmaceuticals, but the low government revenues and the low proportion of public sector spending on health care typical of developing and least-developed countries make this infeasible in most cases. Mobilizing public and private resources is an approach that has been successful in some developing countries such as Thailand<sup>101</sup> and Brazil.<sup>102</sup> It seems unlikely to be feasible in poorer countries like Bangladesh. Substantial international public finance will be needed. One element of such a scheme might be global drugs fund. Efforts to establish such funds are already well underway.

The focus of these efforts is on ensuring affordable access to medicines. So far, there has not been an emphasis on supporting the development of local industries in developing and least-developed countries as a way of achieving this objective. There is no reason for Bangladesh to expect that such public funding schemes would be

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<sup>99</sup> Many developing and least-developed countries that are not obliged to grant patent protection until the expiry of the relevant transition period, nevertheless do grant such protection (*e.g.*, Angola and Mozambique). Also, some patents are not registered in some developing and least-developed countries which offer patent protection.

<sup>100</sup> Oxfam Report, above note 81, Report of Hosbjor Workshop, above note 97; Balasubramaniam, above note 43.

<sup>101</sup> See D. S. Wibulpolprasert, "Mobilization of Domestic Resources for Essential Drugs in Developing Countries: Case Study from Thailand," presented to Workshop on Differential Pricing and Financing of Essential Drugs, Hosbjor, Norway, 8-11 April 2001, describing the combination of measures used including public finance and collective procurement.

<sup>102</sup> Champ & Attaran, above note 5.

targeted to support the Bangladesh industry if a cheaper source of supply existed. In this respect, one source of cheap supply may be the proprietary drug manufacturers themselves. An aspect of the movement to address the global access to medicines crisis has been donations or deep discounting by both patent owners and large generic firms.<sup>103</sup> This is an imperfect solution to the problem of the lack of affordable access to medicines because it depends on the continuing goodwill of donor firms. Nevertheless, such programs could undermine efforts to establish a stronger domestic industry in Bangladesh by reducing demand for industry output. Indeed, it is reasonable to assume that some proprietary drug producers will seek to participate in such programs to the extent that drug donations and discounting can forestall the growth of competing generic producers in countries like Bangladesh.

It should be clear from the foregoing discussion that the implementation of TRIPS rules in Bangladesh and other countries has complex and possibly contradictory implications for the pharmaceutical industry in Bangladesh prior to the requirement for Bangladesh to grant full product patent protection for pharmaceuticals in 2016. The analysis is complicated by the still unresolved question of the extent to which exports of patented products by firms other than the patent owner to address national health care concerns will be permitted under the new TRIPS rules or a new interpretation of existing rules currently being discussed in Geneva. The foregoing discussion sought to identify the categories of TRIPS issues and some of their implications as a framework for policy development. This framework is summarized in the table below. In order to more fully assess the constraints and opportunities created by TRIPS, however, further research needs to be conducted to determine the degree to which patent protection on relevant products actually exists in the developing and least-developed country markets into which Bangladesh's producers may want to export and the prospects for domestic industry to achieve the ability to develop and produce active ingredients for pharmaceutical products.<sup>104</sup> Armed with the results of such research, Bangladesh will be better positioned to advocate for adjustments to TRIPS rules and, more importantly, determine what domestic programs to put in place to promote the local industry.

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<sup>103</sup> "Glaxo to Block Access to Generic Drugs in Ghana," *Wall Street Journal*, 1 December 2000.

<sup>104</sup> A profile of the industry would include, for example, listing of industry participants, their sales, market share, products, sources of supply, production, technical and innovative capacity, and reliance on patents and/or licensing.

**Summary of Strategic Issues Affecting Prospects for the Domestic Pharmaceutical Industry Prior to 2016**

<b>Issue</b>	<b>TRIPS Challenge</b>	<b>Possible Solution</b>	<b>Matters Related to the Solution</b>
Stability of Supply of Therapeutic Ingredients to the Bangladesh pharmaceutical industry	WTO Members with strong generic industries that supply Bangladesh must give full patent protection by 2005 – reducing availability and increasing price of therapeutic ingredients to Bangladesh industry	1. WTO adopts amendment or agreed understanding of TRIPS to permit export of therapeutic ingredients to Bangladesh to promote health without consent of patent owner	- Stability of supply depends on few restrictions on ability of existing supplier states to grant compulsory licences to export to Bangladesh and low compulsory licence fees - Permission to export to Bangladesh not within Bangladesh's control - Possibility of onerous conditions on Bangladesh's eligibility for exports, including restrictions on re-export
		2. Develop Bangladesh's capacity to produce therapeutic ingredients through foreign and domestic investment	- Incentive for generic producers in countries that must impose full patent protection by 2005 to invest in production of generic drugs in Bangladesh - Investment encouraged by tight restrictions on availability of compulsory licenses permitting existing producers of generic therapeutic ingredients to export to Bangladesh under Solution 1 - Need for public and private investment and technical assistance
Demand for Generic Pharmaceutical Products Produced by Bangladesh	1. WTO Members with strong generic industries must give full patent protection by 2005 – reducing ability to compete with Bangladesh products	No solution required	- Requirement to give full patent protection may be avoided by amendment or agreed understanding of TRIPS to permit generic producers in developing countries to export generic products to promote health without consent of patent owner in liberal circumstances
	2. Patent protection required in export markets <ul style="list-style-type: none"> <li>• Developing countries and transition economies (2005)</li> <li>• LDC's (2016)</li> </ul>	Export to (i) non-WTO Members that do not grant patent protection or (ii) Members that do not grant patent protection for relevant products or have issued compulsory licence to import from Bangladesh	- Low demand resulting from weak public and private spending and donations and deep discounting by patent holders may reduce export market potential - Development of global drug funds and other sources of public finance for drugs may increase export opportunities

## 2. After 2016 – Designing a Patent Law for Development

### *Introduction*

After the expiry of the transition period in 2016 or whatever later date is agreed to, the situation for Bangladesh dramatically changes. In order to comply with its TRIPS obligations, Bangladesh must provide full patent protection for pharmaceutical products. Inevitably, this will mean that access to medicines will be impeded, prices will increase and generic drug producers will have to seek the permission of patent owners to continue to produce some of their products.<sup>105</sup> More specifically, licences will have to be obtained by Bangladeshi firms from patent owners to import patented therapeutic ingredients and to permit the manufacture and sale of the resulting finished drugs. The full weight of these changes may be mitigated if Bangladesh were to issue compulsory licences to import therapeutic ingredients from countries that either issue compulsory licences to export generic versions of these ingredients or otherwise permit the export of generic drugs to Bangladesh in accordance with TRIPS, and to permit parallel importing of therapeutic ingredients lawfully sold in other jurisdictions. To the extent that the local industry has developed the capacity to produce therapeutic ingredients and finished products which are subject to patents, after 2016, continuing such production will require either a compulsory licence from the state or a negotiated licence from the patent owner.

Export markets for goods produced under compulsory licence in Bangladesh will be more constrained, consisting only of those countries that are not WTO Members and do not grant patent protection or are WTO Members who must grant patent protection but are willing to grant compulsory licences for import.<sup>106</sup> In terms of patent rules, the export opportunities will be the same for Bangladesh products as for those produced in all other WTO Members. The special incentive for foreign investors to move production of generic products from developing countries to Bangladesh beginning in 2005 will end in 2016. Bangladesh will have an unqualified interest in TRIPS rules permitting Members to authorize exports without the patent owner's consent on the most liberal terms, so as to be able to continue to serve some developing country and least-developed country markets prior to 2016.

The significant new question that arises with respect to the period following 1 January 2016 is what are the possibilities for designing Bangladesh's patent rules to ensure the continuing viability of the local pharmaceutical industry? TRIPS implementation will require substantial changes to the existing patent law. In this section, some of the features of a revised development friendly patent law are identified.<sup>107</sup> In general, Bangladesh should seek to limit the monopoly of patent owners, most of whom will be foreign, to permit the widest possible scope for the development and commercialization of competing products by others in Bangladesh.

### *Limit Breadth of Patent Claims*

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<sup>105</sup> Barton Commission, above note 12, at 37.

<sup>106</sup> As noted above, the question of whether WTO Members may permit the entry of drugs produced under a compulsory licence is not resolved.

<sup>107</sup> See generally, Barton Commission, above note 12; Balasubramaniam, above note 43, describing the measures suggested in the *Human Development Report 2001*, above note 55; and Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (Geneva: South Centre, 2000)[Correa].

The claims made in a patent application regarding an invention are what define the scope of a patent monopoly. The broader the claims that an inventor can make under national law, the wider the monopoly the inventor can obtain. Broad claims reduce the scope for competing products in the market, whereas narrow claims create greater opportunities for innovation and competition. National laws vary in the nature and breadth of claims permitted. In relation to pharmaceutical products claims can be restricted to the chemical structure or composition of a new product. In some countries, like the United States, and, to a limited extent, the European Union, claims may go beyond the structure of the product to include its function.<sup>108</sup> The TRIPS Agreement is silent on the form of and limits on allowable claims and so Bangladesh would be free to adopt a patent law that requires that pharmaceutical patent claims be limited to the precise chemical composition of the product.<sup>109</sup>

As well, once a patent is granted, under TRIPS, it is left up to the national government to determine whether products not literally within the words of a patent claim are nevertheless equivalent to the patented product and so infringe the patent. In the United States, a broad notion of what is equivalent is employed, strengthening the market power of patents. Like other countries, Bangladesh law could provide that claims must be interpreted narrowly to permit the broadest possible scope for the development and marketing of competing products.<sup>110</sup>

### ***High Thresholds of Novelty and Inventive Step***

TRIPS contemplates that the requirements for patentability include novelty, meaning that the invention is not already part of the existing state of the art, and represents an inventive step, meaning that the invention would not be obvious to someone skilled in the relevant trade. The Agreement does not, however, prescribe the contents of these requirements and national approaches differ. By defining these thresholds as imposing high standards for patentability, Bangladesh could ensure that trivial improvements in technology do not benefit from the strong protection provided by patents. It is a common practice of patent owners in the pharmaceutical sector to seek to extend the effective duration of patent protection by obtaining a second later patent on a new mode of delivery of a patented drug (such as capsules instead of tablets) or some other small change in a patented product. Setting high standards for novelty and inventive step would help to ensure that a patent on a product was not, in effect, extended by a subsequent patent on a trivial improvement.<sup>111</sup> Limiting the availability of patents in this way will promote competition in the marketplace. While setting high thresholds for patentability would exclude from patentability local

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<sup>108</sup> These differences were recently described in “Drug Patents: Make love not war – Viagra under threat,” *The Economist*, 8 March 2003, 60.

<sup>109</sup> Because TRIPS prohibits discrimination between fields of technology (Art 27.1), Bangladesh could not enact a patent law that adopted a restrictive approach to claims, which was limited to pharmaceutical products.

<sup>110</sup> The Barton Commission, above note 12, at 49, recommends such a strategy.

<sup>111</sup> The *Patent Act and Designs Act, 1911*, has a provision addressing this issue (s. 15A, added by Act VII of 1930, s. 11). Correa, above note 107, describes a variety of other ways in which proprietary drug producers may seek to extend the effective term of patent protection by separately patenting an element of an already patented product or patenting a different form of what is fundamentally the same product (at 52-7).

inventions which did not meet them, it may be possible to set up another form of lesser *sui generis* protection for such minor inventions.

In setting a high standard for novelty, Bangladesh should consider specifying that in order to be novel, the state of the art includes knowledge developed by or in the possession of the local community in Bangladesh, including traditional knowledge.<sup>112</sup> This should help protect traditional knowledge from being appropriated by patent owners.<sup>113</sup>

### ***High Level of Patent Disclosure***

As discussed at the beginning of this paper, full disclosure of information regarding an invention is a fundamental aspect of the tradeoff between the interests of the patent holder and the public. Indeed, Article 29 of TRIPS requires that Members require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date...Bangladesh should take full advantage of this provision and require that the best known mode for carrying out the invention be disclosed and that the disclosure must enable the execution of all embodiments of the invention.<sup>114</sup> Again, such a requirement will facilitate innovation and the development of competing products.

### ***Exceptions to Exclusive Patent Rights***

As discussed above, Article 30 of TRIPS permits Members to create limited exceptions to patent rights in some circumstances. The *Canada-EU Patents* case, discussed above, suggests a general approach to the interpretation of Article 30. Under this approach, there remains considerable flexibility for Bangladesh to put in place exceptions. Many such exceptions, such as an exception for experimental use, are commonly found under national patent laws. An experimentation exception is most valuable in countries with domestic industries with strong innovative capacity. Other sorts of exceptions may be of greater interest to Bangladesh. The regulatory review exception upheld in the *Canada-EU Patents* case,<sup>115</sup> for example, promotes the entry of generic pharmaceuticals into the market and so may be a more important feature to include in Bangladesh's patent law.

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<sup>112</sup> Correa, *ibid.*, at 43.

<sup>113</sup> In the Doha Declaration on TRIPS and Public Health, above note 7, the TRIPS Council was directed to look at the relationship between TRIPS and the protection of traditional knowledge. Since Doha, there have been extensive discussions in the TRIPS Council regarding the problem of patenting traditional knowledge and how to address it. One suggestion has been to create a database of traditional knowledge that patent examiners may have access to for the purpose of ensuring that a patent is not inadvertently issued covering such knowledge. Peru has suggested creating a system of *sui generis* protection for traditional knowledge. See Minutes of TRIPS Council Meeting held June 25-27, 2002 (IP/C/M/36/Add.1).

<sup>114</sup> Because production will usually not have commenced at the time the application is filed, the disclosure may not be sufficient to permit a third party to reproduce the invention. In Canada, Vaver has argued that the requirements for and practice of drafting Canadian patent claims is such that it is often impossible for persons with access to the claim to reproduce the invention (D. Vaver, "Intellectual Property Today: Of Myths and Paradoxes," (1990) 69 Can. Bar Rev. 98 at 123-124).

<sup>115</sup> Also known as an "early working" or, in the United States, as a "Bolar Exception".

Parallel imports are another form of exception to the exclusive rights of the patent owner which should be permitted, though the benefits are likely to be small. Parallel imports would permit inexpensive drugs legitimately sold in other national markets to enter the country and be sold free of the claims of the patent owner. Parallel importing could enhance access to patented ingredients which can be assembled into final products by the Bangladesh industry. The significance of permitting parallel importing will depend on the extent to which such products are sold in other markets and at what prices. As a matter of general policy, however, with respect to therapeutic ingredients, there would be no reason not to permit parallel importing.

By contrast, to the extent that imports are finished goods to be sold in competition with the products of the domestic industry, parallel importing may threaten domestic producers. Again, the magnitude of this effect will depend upon what drugs are sold at what prices in other countries.

It is possible to conceive of a parallel importing policy for Bangladesh that distinguishes between these two types of parallel imports. However, such a policy may be found to be inconsistent with Bangladesh's TRIPS obligation to provide patent protection without discrimination as to the field of technology under Article 27.1. In practice, any such policy may be hard to enforce and, most important, would be directly contrary to the goal of providing affordable access to medicines for the population.<sup>116</sup> On balance, permitting unrestricted parallel importing would seem the best policy.

### ***Strong Compulsory Licensing***

More elaborate provisions on compulsory licensing than exist in the current law will be a necessary feature of Bangladesh's patent law after 2016.<sup>117</sup> With the imposition of patent protection, a licence from the patent owner will be needed both to import patented therapeutic ingredients and to permit the production of patented products. Compulsory licensing can be used to permit these activities where voluntary consent is not forthcoming subject to the requirements of TRIPS. As discussed above, TRIPS permits Members to determine the grounds upon which compulsory licences may be issued though it establishes a long list of conditions which must be satisfied before a licence is permitted.

One controversial ground for issuing a compulsory licence is "local working." From the perspective of developing the local pharmaceutical industry in Bangladesh, a requirement that the patent actually be used for production in the country could encourage foreign direct investment in local production with its attendant benefits in terms of employment and technology transfer. Some have interpreted Article 27.1 of

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<sup>116</sup> This conflict between policies which may benefit the domestic industry but which may impede affordable access to medicines is discussed below. See notes 127-134 and accompanying text. A related issue associated with parallel importing is its impact on market segmentation and tiered pricing schemes which, in general, would provide developing country consumers with cheaper products. Some have expressed a concern that permitting parallel importing would reduce the effectiveness of segmenting markets (e.g. H.E. Bale, "Access to Essential Drugs in Poor Countries – Key Issues – The Industry Perspective" presented to Workshop on Differential Pricing and Financing of Essential Drugs, Høsbjør, Norway, 8-11 April 2001 [Bale]).

<sup>117</sup> Bangladesh's current *Patent and Designs Act, 1911* already has a provision dealing with compulsory licensing, but it should be expanded in the ways described.

TRIPS which gives the patent holder the exclusive right to import product into a national market as inconsistent with granting compulsory licences where the patent owner would be willing to supply the market through imports.<sup>118</sup> However, there is no express prohibition on granting a compulsory licence based on failure to work the patent in a country and it is not obvious that this interpretation is right.<sup>119</sup> Where a patent owner was willing to supply the Bangladesh market through imports, it may still be more desirable to issue a compulsory licence where Bangladesh producers would be able to produce at lower cost and offer drugs for lower prices.<sup>120</sup> The feasibility of compulsory licensing will, in turn, depend on whether the local firms have the capacity to exploit the licence.

Less controversial grounds for issuing compulsory licences are contemplated in TRIPS itself:

- To correct anticompetitive practices,
- National emergency or other situations of extreme urgency, including public health crises, and
- Public non-commercial use, such as to provide health care to the poor.

In all these circumstances, TRIPS Article 31 permits a Member to grant compulsory licences without having to first make efforts to obtain a licence from the patent owner on reasonable commercial terms and conditions. Even in these cases, however, TRIPS requires the payment of “adequate remuneration in the circumstances of each case, taking into account the economic value of the [licence].” Any compulsory licensing system implemented by Bangladesh must determine how remuneration to the right holder is to be assessed. Obviously, the rate of remuneration will have a substantial impact on the ability of the licensee to exploit the licence and on the feasibility of using compulsory licensing as an alternative to voluntary licensing or direct supply by the patent owner. Internationally, the approach to remuneration is variable. In some countries, compulsory licence rates are a fixed percentage of net sales by the licensee.<sup>121</sup> In other countries, the rate is determined by reference to what a willing licensor would accept from a licensee. So long as the rate is “adequate” as required in Article 31, Bangladesh has significant flexibility in determining what is an appropriate.<sup>122</sup> Bangladesh should provide that royalty rates should be determined by reference to the value of the licensed use in Bangladesh, rather than in more expensive markets. As well, the law should provide that the rate may be reduced or eliminated where the licence is granted to remedy anticompetitive behaviour as expressly permitted by TRIPS Article 31.

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<sup>118</sup> Bale, above note 116.

<sup>119</sup> The *Patents and Designs Act, 1911* permits the revocation of a patent not being worked in Bangladesh.

<sup>120</sup> Where the Bangladesh producer will sell drugs at higher prices, the need to promote access to medicines would dictate that no compulsory licence be issued. This is unlikely to occur in practice.

<sup>121</sup> For example, in Canada prior to 1993, the rate was 4%.

<sup>122</sup> As discussed above in relation to the *Canada-EU Patents* case, above note 32, where there is no consistent international practice regarding how an issue is to be resolved, a WTO dispute settlement panel is likely to accord deference to the solution chosen by a Member. As well, it may be that the cost of compulsory licence fees paid by the state will be offset in the long term by a reduction in state expenditures on health care. Brazil’s program of providing drugs to HIV/AIDS patients has been found to have this effect. See Barton Commission, above note 12, at 43.

One issue, which will affect the economic value of the licence, is whether it permits the export of pharmaceuticals. As discussed above, the rules defining when a compulsory licence to export may be granted, notwithstanding the operation of TRIPS Article 31(f), have yet to be finally agreed. Post 2016, the Bangladesh pharmaceutical industry will have a new and unqualified interest in liberalized conditions for such licences, because Bangladesh firms will have to obtain them to export to most other markets.<sup>123</sup> Bangladesh's patent law should take maximum advantage of whatever flexibility is agreed to by the Members of the WTO.

The benefits of compulsory licensing may be lost if marketing approval for a product produced under a compulsory licence is made more difficult because the generic drug producer has restricted access to test data developed by the patent owner for the purpose of obtaining marketing approval for the patented drug. TRIPS Article 39.3 obliges Members to protect confidential test or other data that they require to be submitted as a condition of approving the marketing of a pharmaceutical product against unfair commercial use if the development of the data required considerable effort. This obligation applies only to new chemical compositions.<sup>124</sup> The Barton Commission has recently suggested that, notwithstanding this provision, TRIPS permits Members to approve generic drugs based on the test data submitted by the patent holder. While this may be an aggressive interpretation of TRIPS, it is one way that Bangladesh may design its patent laws so as to facilitate generic competition.<sup>125</sup>

Under the laws in some countries, such as Canada, a generic drug may be approved for marketing on the basis that it is similar to an approved patented drug.<sup>126</sup> This does not necessitate relying on the data submitted by the patent holder, but simply comparing the generic drug with the approved patented drug. This Canadian approach is consistent with TRIPS and could be adopted by Bangladesh.

## **THE LIMITED IMPACT OF PATENT RULES AND THE ROLE OF COMPLEMENTARY RULES**

This paper has focused on the TRIPS framework for patent laws both in Bangladesh and in other countries, and impact of TRIPS compliant national patent laws on the prospects for the development of the Bangladesh pharmaceutical industry and on the scope for Bangladesh to shape its own patent law most effectively to enhance these prospects. It is essential to recognize, however, that there are significant limits on the impact of patent rules on the domestic industry. The two most important are the limited application of drug patents to drug products sold in the marketplace and the

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<sup>123</sup> As noted above, export markets are likely to be more limited beginning in 2016. Since all WTO Members will have to provide patent protection, only non-WTO Members and WTO Members which either have issued compulsory licences to import or permit entry of products produced under compulsory licence under their parallel importing rules will be able to import Bangladesh products produced under compulsory licences.

<sup>124</sup> Patent systems are expensive to set up and maintain. Bangladesh will need to take steps to ensure that its patent system is streamlined and procedural to minimize costs of administration. This will become especially important with the extension of patents to pharmaceutical products, since pharmaceutical companies are the heaviest users of the patent system. Correa, above note 107 discusses some ways in which the burden of dealing with patent applications may be reduced (at 83-85).

<sup>125</sup> Barton Commission, above note 12, at 50.

<sup>126</sup> *Bayer Inc. v. Canada Attorney-General*, [1999] Federal Court Judgments No. 826.

prospect that some patent rules that Bangladesh could adopt to promote the development of the domestic pharmaceutical industry may conflict with the overriding public policy objective of providing affordable access to medicines to the population.

Many essential drugs are off patent. Of the drugs on the World Health Organization Essential Drugs list, 75% are not currently the subject of patent protection.<sup>127</sup> As well, even after 2016, when Bangladesh must grant patent protection for pharmaceuticals, it will not have to grant patents to any drug put on the market before 1996. For any drug put on the market between 1996 (the date TRIPS came into force) and 2016, a patent need only be granted after 2016 if the person who was entitled to the patent filed a mailbox application in Bangladesh prior to the introduction of the drug into the market.<sup>128</sup> As discussed above, if no mailbox application has been filed, a drug sold in the market place without valid patent protection will not meet the novelty requirement.<sup>129</sup> Because only a fraction of drugs are subject to patents, patent rules will have a limited impact on the prospects for the domestic industry.

For the same reason, patents will have a limited effect on prices paid by consumers. Many factors other than the existence of patent protection on a drug will have an impact on price. The buyer's market power, competition between producers, transparency of procurement (lack of corruption), obstacles to trade diversion and the volume and duration of purchases are all factors affecting prices.<sup>130</sup> As well, factors including sustainable and adequate financing, reliable health care and supply systems as much as affordable prices will affect access to medicines in Bangladesh and elsewhere.<sup>131</sup>

Notwithstanding the limited impact of patent rules on the domestic industry and on access to medicines, in some circumstances, patent rules that will best promote the interests of the domestic industry may imperil access to medicines. As a consequence, a single-minded focus on the domestic industry risks losing sight of the fundamental problem of ensuring affordable access to medicines.

For example, Bangladesh may want to support tight restrictions on the ability of India and others to grant compulsory licences to export therapeutic ingredients to Bangladesh beginning in 2005 when they are required to put in place full product patent protection in order to encourage generic producers in these to jurisdictions to move their production to Bangladesh. Until 2016, tight restrictions will also inhibit the ability of these producers to compete in certain export markets with products from Bangladesh. At the same time, however, access to medicines in Bangladesh may not be promoted by such restrictions. Compulsory licensing, at least in the short term, might result in lower domestic prices.

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<sup>127</sup> Barton Commission, *ibid.*, at 35.

<sup>128</sup> As discussed above this is only true because Bangladesh is not required to grant exclusive marketing rights. See note 72 and accompanying text.

<sup>129</sup> It is also true, however, that the increasing number of drugs, which are immune to existing drugs, will make new drugs more important. These new drugs will be subject to patent protection. See Oxfam Report, above note 81.

<sup>130</sup> *Ibid.*

<sup>131</sup> Report of Hosbjor Workshop, above note 98.

Another example of possible tension between efforts to support the development of the domestic industry and access to medicines arises relate to donations or substantial price reductions in pharmaceuticals supplied by proprietary drug producers. In the past several years, there have been examples of multinational drug firms donating or deeply discounting drugs supplied to developing countries. Their willingness to do so reflects, undoubtedly, recognition of the reputational benefits of such gestures, as well as the practical reality that most of the consumers in such markets will be unable to pay a sufficiently high price to make their commercial exploitation of the market worthwhile. In some developing countries with established pharmaceutical industries, governments have been successful in inducing donations and discounts by the threat of compulsory licensing.<sup>132</sup> Developing the capacity of the Bangladesh industry to create and produce generic pharmaceuticals would enhance the bargaining leverage of the Bangladesh government in this way. Use of a credible threat of compulsory licensing to induce large-scale donations or deep discounting by multinational drug firms will enhance access to a source of needed medicines at reduced prices. At the same time, however, the industry will be precluded from supplying the same medicines.

In short, when designing policies to promote the development of the pharmaceutical industry in Bangladesh, the limited impact of patent rules must be recognized. Complementary policies relating to taxation, investment and other areas will be required. As well, government policy must reconcile the interests of the domestic industry with the larger societal interest in affordable access to medicines. Working toward the critical public policy goal of improved access to medicines may constrain the ability of Bangladesh to promote the domestic industry to some extent.

## CONCLUSION

Even though there are other factors affecting the price of pharmaceuticals, it is essential for Bangladesh to pursue the right patent policy. There is no trade-off between patent policy and other policy measures directed to other aspects of ensuring affordable access to medicines.<sup>133</sup> One way that patent rules will affect affordable access to medicines is their effect on the Bangladesh pharmaceutical industry, the principal supplier of drugs to the population. This paper examined the prospects for the development of the domestic industry in light of current and possible future WTO rules on the patent protection of pharmaceuticals.

For Bangladesh, there is little to be gained by moving to full patent protection for pharmaceutical products prior to the latest date permitted by TRIPS, currently, 1 January 2016. Prior to granting full patent protection, the prospects for the growth of the Bangladesh industry depend on the stability of supply of therapeutic ingredients and the likely demand for Bangladesh production. Supply will be constrained beginning in 2005 when the large producers of generic drugs in India and elsewhere must themselves begin to give full patent protection for pharmaceuticals. This problem is likely to be mitigated, at least to some extent by changes to the TRIPS regime, or, at least, an agreed understanding of the current TRIPS rules that will permit Indian and other generic producers to export to Bangladesh under compulsory

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<sup>132</sup> See Barton Commission, above note 12, at 42.

<sup>133</sup> This is the conclusion of the Barton Commission, *ibid.*, at 39.

licences or some other mechanism. How much this will alleviate the problem will depend on the conditions having to be satisfied in exporting countries and in Bangladesh before such licences are permitted and whether exporting countries exercise their discretion in practice to permit exports to Bangladesh. The WTO has not yet reached a consensus on what these conditions are. Continuing access to imported ingredients will be promoted by minimal conditions

As an alternative to relying other countries permitting exports of therapeutic ingredients, Bangladesh could seek to develop the capacity of the domestic industry to a level at which it would be able to produce its own therapeutic ingredients. Generic producers in India and other countries might be interested in investing in the production of such ingredients in Bangladesh in anticipation of the 2005 deadline, when generic production in their home markets will be severely curtailed. As noted above, imports of ingredients into Bangladesh will be promoted if the WTO imposes few conditions on the ability of these countries to grant compulsory licenses for export to Bangladesh. The opposite is true with respect to investment. Investment will be encouraged by rules that severely restrict the circumstances in which WTO Members may permit their generic producers to export to Bangladesh. Currently there is no consensus at the WTO on a significant relaxation of the constraints on compulsory licensing found in TRIPS. Nevertheless, the operation of the TRIPS rules alone is unlikely to be sufficient to attract foreign investment. Complementary policies, domestic public investment and international support for technology transfer to Bangladesh will all be essential.

The prospects for growth in the domestic industry, including its attractiveness to foreign investors, will also depend on the likely demand for the production of the Bangladesh industry. At least until 2016, there will be least-developed country Members of the WTO where patent protection is not granted. In other national markets compulsory licences to import may be granted or patent protection may not exist for other reasons. Generic producers in WTO Members that must themselves grant product patent protection by 2005 will be unable to continue to supply these markets with products subject to such protection. Moving production to a hospitable host state that does not grant patent protection like Bangladesh may be the only way to continue to serve them.

Investors will have to factor in, however, the very weak purchasing power of many consumers in those markets and the prospects for domestic and international public finance for drug purchases. Perhaps the most difficult factor to assess is the willingness of proprietary drug manufacturers to supply developing country markets at low prices or even through donations in competition with producers in Bangladesh.

As well, within the framework considerations set out above, formulating the right domestic policy will require further research and information gathering. In each prospective export market, it would be necessary to determine issues like what are the patent rights for particular drugs that Bangladesh producers are interested in exporting to the market, and what competitors are able to sell into or produce in that market. Research into the likelihood that the domestic industry can move forward to develop the capacity to produce therapeutic ingredients and develop new generic pharmaceutical product through reverse engineering will be needed.

After 2016, the concerns regarding supply of therapeutic ingredients and demand will be similar, but, in addition, the window for foreign generic producers from other countries to maintain their market access to Bangladesh and other markets not granting patent protection by investing in Bangladesh will be closed. As well, access for Bangladesh's products to export markets will be the same as for products from all other WTO Members.

By 2016, Bangladesh must meet the challenge of developing a patent law which best reflects its interests while complying with the mandates of the TRIPS Agreement. This paper suggests some of the ways in which this may be done. In general, limiting the scope of patents, setting high thresholds for patentability, creating limited exceptions to exclusive rights and strong compulsory licensing provisions will be needed. Whether these development friendly patent rules will benefit the domestic industry will depend significantly on whether the Bangladesh industry has developed the capacity to develop and produce generic drugs locally.

While the development of the domestic industry will not address all impediments to access to medicines in Bangladesh, it may be an important component of any policy to do so. At the same time, a focus on building local expertise, developing innovative capacity or at least imitative capacity in a manner that is consistent with affordable access to medicines has important benefits of its own in terms of investment, employment and technology transfer. The extension to 2016 of the deadline for least-developed countries to grant patent protection for pharmaceutical products and the impending requirement for developing countries to grant protection by 2005 opens a limited and uncertain window of opportunity for the domestic pharmaceutical industry in Bangladesh. The timelines fixed by the WTO suggest that the time to take a hard look at the nature of this opportunity and how the domestic industry can best exploit it is right now. This paper has set out some of the framework considerations for such an assessment.

## **Annex 1 – Selected Articles of TRIPS**

### Article 1

#### *Nature and Scope of Obligations*

...Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice....

### Article 6

#### *Exhaustion*

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of exhaustion of intellectual property rights.

### Article 7

#### *Objectives*

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations.

### Article 8

#### *Principles*

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provide that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

### Article 27

#### *Patentable Subject Matter*

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial

application.<sup>134</sup> Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

- (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
- (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

## Article 28

### *Rights Conferred*

1. A patent shall confer on its owner the following exclusive rights:

- (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing<sup>135</sup> for these purposes that product;
- (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

## Article 30

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<sup>134</sup> For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

<sup>135</sup> This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

*Exceptions to Rights Conferred*

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

*Other Use Without Authorization of the Right Holder*

Where the law of a Member allows for other use<sup>136</sup> of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or

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<sup>136</sup> "Other use" refers to use other than that allowed under Article 30.